top ten
in gastroenterologia
14^ EDIZIONE

24-25 NOVEMBRE 2023

BERGAMO

HOTEL EXCELSIOR SAN MARCO
Piazza della Repubblica, 6

IBD e gravidanza (quale biologico?)

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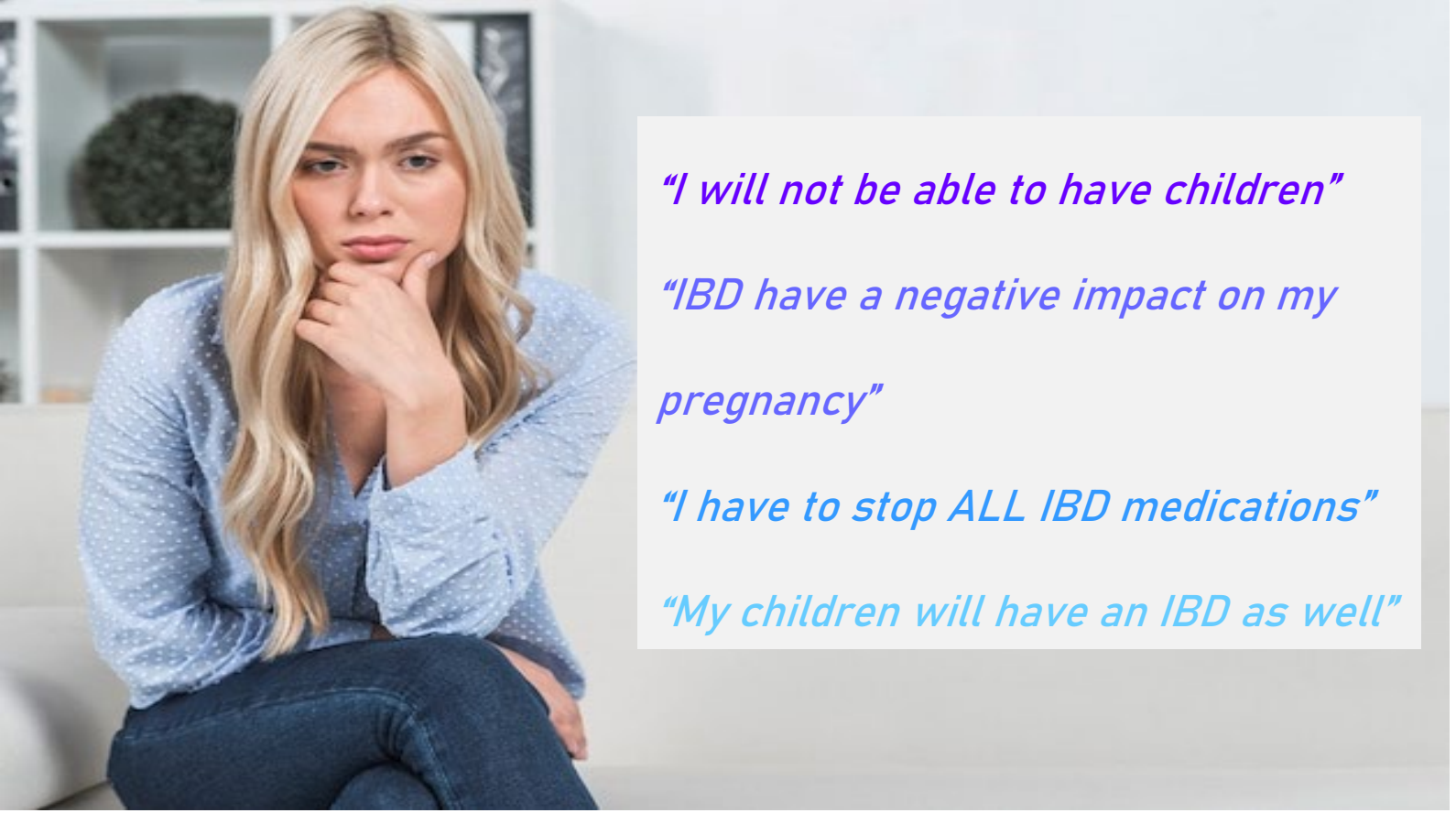
DISCLOSURES

SPA Società Prodotti Antibiotici

Galapagos

Pfizer

I care.



"I will not be able to have children"

"IBD have a negative impact on my pregnancy"

"I have to stop ALL IBD medications"

"My children will have an IBD as well"

ECCO GUIDELINES ON SEXUALITY, FERTILITY, PREGNANCY AND LACTATION

J. Torres et al JCC 2023 17, 1 – 27

1

BEFORE PREGNANCY

- Discuss disease heritability
- Smoking, alcohol and recreational drug cessation
- Ensure cervical cancer screening and vaccinations are updated
- Screen for anemia and vitamin deficiencies
- Folic acid prescription
- Review safety of drugs during pregnancy: stop methotrexate, Jak inhibitors, and ozanimod before conception, and consider alternative therapy to ensure good disease control
- Assess disease activity, optimize treatment to ensure disease remission
- Establish an individualized plan with the patient for disease monitoring and management during pregnancy
- Discuss risk/benefit of drug maintenance during pregnancy and lactation

"The exams for IBD monitoring can cause problems for the baby"

"Colonoscopy is forbidden"

"Now the priority is the child and not the activity of my illness"

"I will have to give birth with a caesarean"

ECCO GUIDELINES ON SEXUALITY, FERTILITY, PREGNANCY AND LACTATION

J. Torres et al JCC 2023 17, 1 – 27

2

DURING PREGNANCY

- Discuss risk/benefit of drug maintenance during pregnancy
- Establish a plan for delivery and mode of delivery
- Monitor with faecal calprotectin and intestinal ultrasound if available
- Monitor for adequate weight gain during pregnancy
- Discuss risk/benefit of drug maintenance during lactation
- Discuss safety of vaccination in the children
- Discuss management plan with family doctor and/or obstetrician

"I can't breastfeed"

"what about vaccines?"

"I feel alone with my child

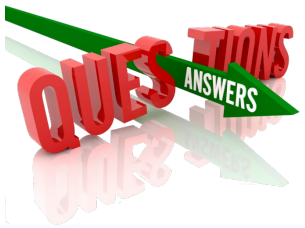
and my illness"

ECCO GUIDELINES ON SEXUALITY, FERTILITY, PREGNANCY AND LACTATION

J. Torres et al JCC 2023 17, 1 – 27

AFTER DELIVERY

- Promptly restart treatment in women that stopped therapy during pregnancy
- Discuss safety of drugs during lactation
- Postpone live vaccines during the first 6–12 months of life in children exposed to biologics in utero, or until levels in children are undetectable
- Screen for mental health problems in the post-partum period



PRE | DURING | POST

- ✓ CONTRACEPTION
- ✓ IMPACT OF PATERNAL AND MATERNAL IBD ON THE RISK OF IBD IN THE OFFSPRING
- ✓ **PRECONCEPTION COUNSELLING**
- ✓ VOLOUNTARY CHILLESSNESS IN IBD
- ✓ **FERTILITY**

Preconception Care Reduces Relapse of Inflammatory Bowel Disease During Pregnancy

Alison de Lima,* Zuzana Zelinkova,*,‡ Annemarie G. M. G. J. Mulders,§ and C. Janneke van der Woude*

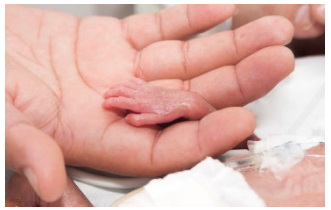
CGH 2016

Table 2. The Effect of Preconception Advice on Behavioral Parameters

Variable	PCC (n = 155)	No PCC (n = 162)	*P*	Crude OR (95% CI)	Adjusted OR (95% CI)
Medication change necessary before pregnancy, n (%)					
No	142 (91.6)	161 (99.4)	.0006	7.54 (1.67–33.98)	7.12 (1.56–32.51)[b]
Yes	13 (8.4)	1[a] (0.6)			
Adequate planning of conception, n (%)					
No	16 (10.3)	-	-	-	-
Yes	95 (61.3)	-			
Correct adherence to IBD medication during pregnancy, n (%)					
No	4 (2.6)	22 (13.6)	.002	5.78 (1.94–17.18)	5.69 (1.88–17.27)[c]
Yes	151 (97.4)	140 (86.4)			
Adequate folic acid intake, n (%)					
No	14 (9.0)	61 (37.7)	.0001	5.71 (3.01–10.86)	5.26 (2.70–10.26)[b]
Yes	118 (76.1)	90 (55.6)			
Quit smoking during pregnancy, n (%)					
No	7 (29.2)	17 (70.8)	.009	5.90 (1.70–20.48)	4.63 (1.22–17.55)[b]
Yes	17 (70.8)	7 (29.2)			
Alcohol intake during pregnancy, n (%)					
No	125 (80.6)	151 (93.2)	1.00	0.81 (0.22–2.92)	0.74 (0.20–2.71)[b]
Yes	4 (2.6)	6 (3.7)			

PRECONCEPTION CARE REDUCES

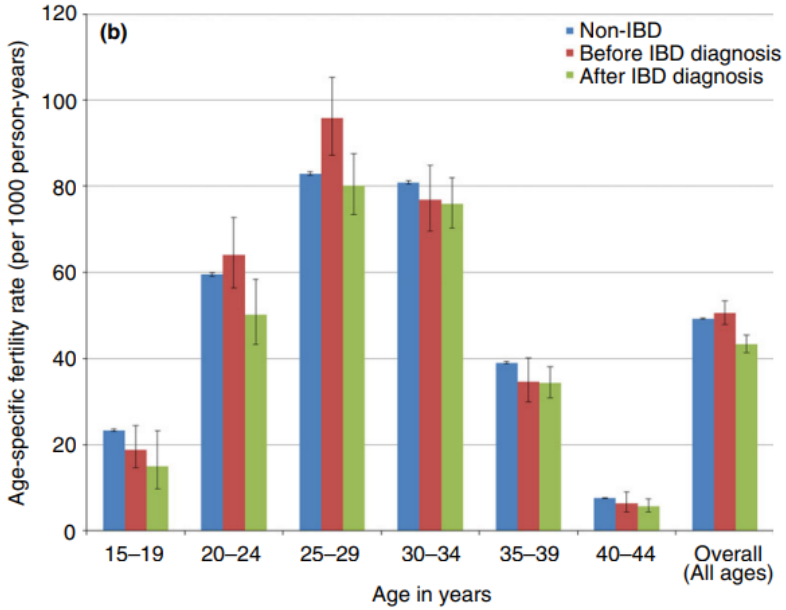
- ✓ IBD relapse by promoting adherence to medication and smoking cessation
- ✓ risk for babies of low birth weight



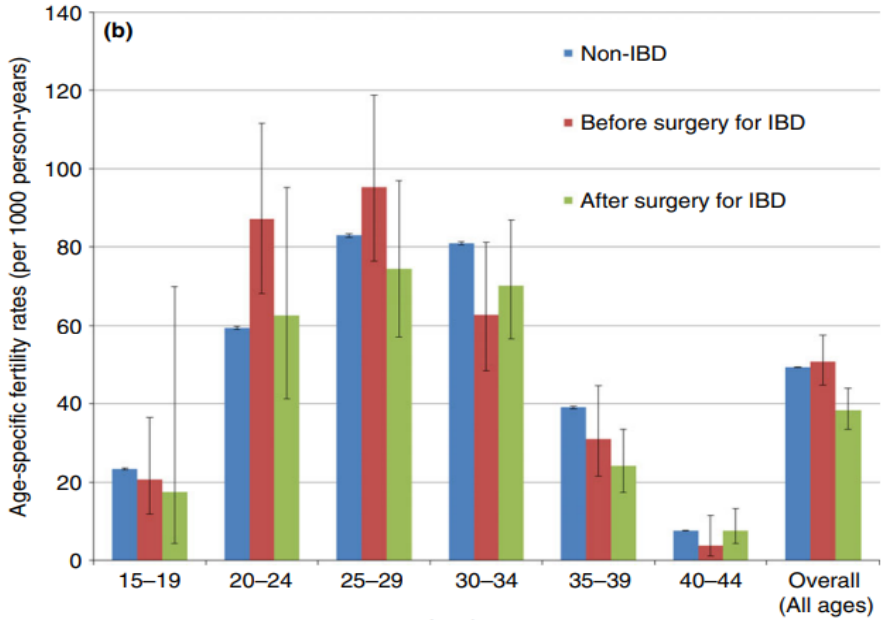
Decreased fertility rates in 9639 women diagnosed with IBD: a United Kingdom population-based cohort study

9639 women with IBD aged 15–44 years in 1990–2010 from a UK primary care database *Ban APT, 2015*

BEFORE AND AFTER IBD DIAGNOSIS



BEFORE AND AFTER IBD SURGERY



Women with IBD have marginally lower fertility rates. These rates decreased following flares and surgical interventions.

"Active disease is associated with decreased fertility in women with IBD"

IBD and PREGNANCY
(IN DREAMLAND ?)

Disease management

- 3-month steroid-free remission prior to conception
- Confirm remission with endoscopy or other objective markers

Medication management

- Stop methotrexate ≥ 3 months prior to conception
- Continue mesalamine
  - Sulfasalazine requires 2 mg folic acid daily
- Taper off corticosteriods
- Continue azathioprine monotherapy
- Continue biologic therapy
  - Measure serum drug levels
  - Consider risk/benefit of stopping concomitant azathioprine
- Tofacitinib: avoid or use with caution

PRECONCEPTION

Healthcare maintenance

- Up-to-date Papanicolaou smear
- Vaccines
- Cessation of drugs, alcohol and tobacco
- Taper off opioids
- Colon cancer surveillance
- Achieve healthy weight
- Start a prenatal vitamin
- Standard preconception health care (as per ACOG guidelines[121])
- Effective contraception (LARC)

MULTIDISCIPLINARY TEAM

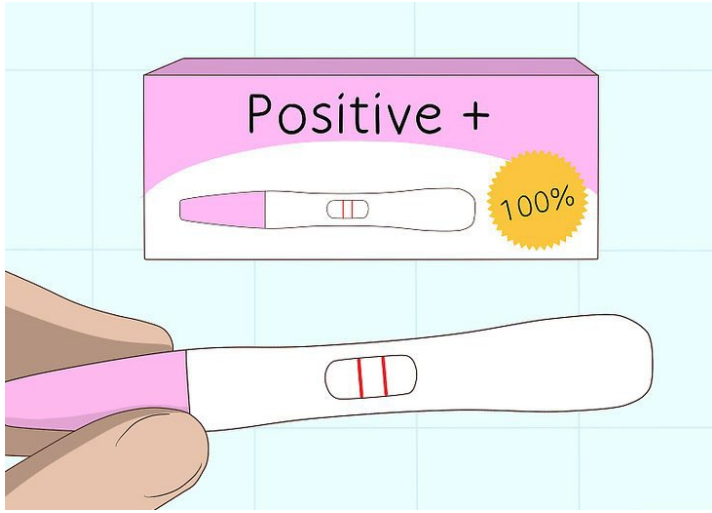
- ✓ gastroenterologist
- ✓ gynecologist
- ✓ obstetrician
- ✓ paediatrician
- ✓ psycologist
- ✓ nutrinionist
- ✓ surgeon
- ✓ lactation counselor

Interdisciplinary consultation

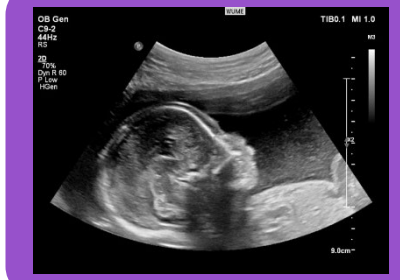
- Nutrition: ensure adequate caloric intake and vitamin levels
- MFM: history of prior pregnancy complication
- Colorectal surgeon: history of IPAA or ostomy

PRE | DURING | POST

- ✓ MONITORING OF IBD DURING PREGNANCY
- ✓ THROMBOEMBOLIC COMPLICATIONS DURING PREGNANCY
- ✓ IBD FLARES DURING PREGNANCY
- ✓ SURGERY IN PREGNANT WOMEN
- ✓ DRUGS DURING PREGNANCY
- ✓ MODE OF DELIVERY



MONITORING



Monitoring of pregnancy

Monitoring of IBD
(disease and medications)

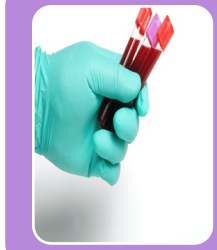
Monitoring of nutrition and weight gain

Eur J Intern Med. 2020 Jul;77:105-110. doi: 10.1016/j.ejim.2020.03.015. Epub 2020 Mar 17.

Clinical utility of fecal calprotectin in monitoring disease activity and predicting relapse in pregnant patients with inflammatory bowel diseases

Amihai Rottenstreich [1], Tali Mishael [2], Sorina Grisaru Granovsky [2], Benjamin Koslowsky [2], Hagai Schweistein [2], Guila Abitbol [2], Eran Goldin [2], Ariella Bar-Gil Shitrit [2]

Conclusion: FC appears to be a reliable marker of ongoing disease activity throughout the prenatal course as well as a predictor of imminent disease flare among IBD pregnant patients.



Monitoring of IBD

how?

Observational Study > Inflamm Bowel Dis. 2017 Jul;23(7):1240-1246.
doi: 10.1097/MIB.0000000000001136.

Fecal Calprotectin Is Not Affected by Pregnancy: Clinical Implications for the Management of Pregnant Patients with Inflammatory Bowel Disease

Mette Julsgaard [1], Christian L Hvas, Richard B Gearry, Thea Vestergaard, Jan Fallingborg, Lise Svenningsen, Jens Kjeldsen, Miles P Sparrow, Signe Wildt, Jens Kelsen, Sally J Bell

Conclusions: The physiological changes that occur during pregnancy do not affect FC, in contrast to CRP and HBI/SCCAI. The combined use of FC and PGA seems optimal to assess disease activity in IBD during pregnancy.

SERUM BIOMARKERS

- ✓ haemoglobin
- ✓ albumin
- ✓ C-reactive protein (CRP)
- ✓ FAECAL CALPROTECTIN

Monitoring - *when?*

IBD Remission

- ✓ GI visit every trimester and as needed
- ✓ complete blood test and FCP every visit

Maternal/fetal monitoring

- ✓ Gyn and obstetrician visit and growth ultrasound based on national guideline
- ✓ counseling on delivery

IBD Flare

- ✓ GI follow-up every 2 weeks
- ✓ adjust medication
- ✓ monitor labs and FCP
- ✓ strumental evaluation

Maternal/fetal monitoring

- ✓ fetal growth surveillance every 4 weeks
- ✓ US cervical lenght screening (18-22 wks)
- ✓ nutrition counseling
- ✓ Pt on steroids should have early glucose screen
- ✓ Counseling on delivery

Mahadevan et al Gastroenterology 2019

FLARE MANGEMENT DURING PREGNANCY

Pregnant women who have new symptoms suggestive of IBD, or those experiencing a flare, may be considered for diagnostic imaging.

Table 1. Options for Flare Management[61–64,115–120]

Laboratory values	Endoscopy	Radiologic imaging	Surgery	Medication
Standard IBD laboratory values checked Trends for CRP and ESR may be helpful Fecal calprotectin Serum drug concentrations Possibly elevated in pregnancy: ESR CRP Alkaline phosphatase (also elevated in lactation) Reduced in pregnancy: Hemoglobin Albumin	Perform for strong indications: Determining IBD disease activity When result will change management Flexible sigmoidoscopy is preferred over pan-colonoscopy when possible; can be performed unsedated, unprepped, and in any trimester	MRI and CT have similar diagnostic accuracy for assessing IBD Gadolinium should be avoided in pregnancy The cumulative radiation exposure of a single CT scan (about 50 mGy) is below the level of concern Ultrasound, where available is appropriate for terminal ileal disease	Surgical intervention may be needed for: Acute refractory colitis Perforation Abscess Severe hemorrhage Bowel obstruction	Manage similar to nonpregnant IBD patients Exceptions: Thiopurine-naïve patients: avoid first start in pregnancy due to concerns for distinctive rare adverse reactions Methotrexate contraindicated Tofacitinib: avoid due to limited human data

CRP, C-reactive protein; CT, computed tomography; ESR, erythrocyte sedimentation rate; MRI, magnetic resonance imaging.

Full colonoscopy, as well as any sedated procedure performed after 24 weeks, requires a documented discussion with the patient about fetal monitoring and possible need for emergent cesarean section.

Mahadevan et al Gastroenterology 2019

Does lower gastrointestinal endoscopy during pregnancy a risk for mother and child?

Table 1 First trimester fetal and maternal adverse events (wk 1–12)

Indication	N	Maternal adverse events	Pregnancy outcome	Spontaneous abortion	Other fetal adverse events	Temporal relation with endoscopy?	Etiological relation with endoscopy?
Colonoscopy							
IBD & colitis other [21-27]	12	None	Live births (n = 11), stillbirth (n = 1)	No (n = 12)	2 premature births (32 and 33 wks), 1 stillbirth (22 wks)	Unclear, paper fails to show which outcome belongs to which patient	No, authors do not link adverse events to endoscopy

Table 2 Second trimester fetal and maternal adverse events (wk 13–26)

Indication	N	Maternal adverse events	Pregnancy outcome	Premature births	Other fetal adverse events	Temporal relation with endoscopy?	Etiological relation with endoscopy?
Colonoscopy							
IBD & colitis other [24,52-54]	6	None	Live birth (n = 5), stillbirth (n = 1)	Yes(n = 2), No (n = 4)	Unreported (n = 2), none (n = 4)	Unclear, paper fails to show which outcome belongs to which patient	Unclear, authors do not link adverse event (stillbirth) to endoscopy

Table 3 Third trimester fetal and maternal complications (27–42 wks)

Indication	N	Maternal adverse events	Pregnancy outcome	Premature birth	Fetal adverse events	Temporal relation with endoscopy?	Etiological relation with endoscopy?
Colonoscopy							
IBD & colitis other [21-27]	12	None	Live births (n = 11), stillbirth (n = 1)	No (n = 12)	2 premature births (32 and 33 wks), 1 stillbirth (22 wks)	Unclear, paper fails to show which outcome belongs to which patient	No, authors do not link adverse events to endoscopy

Systematic review
82 studies

endoscopy during pregnancy is of low risk in all three trimesters of pregnancy

De Lima et al. BMC Gastroenterology 2015

"EUS can be performed, but it is not useful in the third trimester"

"MRI without Gadolinium can be performed, in case of suspected flare"

"endoscopy can be performed when needed to guide clinical decision making "

"capsule endoscopy is considered a contraindication"

But we have to keep in mind..

Torres J et al JCC 2022
Choden T et al WJG 2018
Lima et al. JCC 2015

- ✓ procedure time should be minimized
- ✓ colon cleansing agents in the pregnant population insufficient data (NO phosfate preparation)
- ✓ the lowest effective dose of sedative medications is recommended (in standard concentration at any gestational age, NO teratogenic effect., avoid Bzd)
- ✓ The decision and the methods used to monitor foetal heart rate depend on gestational age of the foetus and available resources
- ✓ patient should be kept in left pelvic tilt or left lateral position to avoid vena cava or aortic compression

Review > Gut. 2007 Jun;56(6):830-7. doi: 10.1136/gut.2006.108324. Epub 2006 Dec 21.

A meta-analysis on the influence of inflammatory bowel disease on pregnancy

J Cornish [1], E Tan, J Teare, T G Teoh, R Rai, S K Clark, P P Tekkis

Table 2 Pregnancy outcomes in inflammatory bowel disease versus controls

Outcome of interest	No of studies	Patients with IBD (n)	Controls (n)	OR (95% CI)	p Value	HG χ^2	HG p value
IBD *v* Control							
LBW	3	1033	239 864	2.10 (1.38 to 3.19)	**<0.001**	3.87	0.14
Premature birth	8	1716	298 105	1.87 (1.52 to 2.31)	**<0.001**	9.4	0.23
SGA	4	1097	240 931	1.87 (0.61 to 5.7)	0.27	52.36	**<0.001**
Still births	4	1243	240 931	1.48 (0.89 to 2.47)	0.13	11.43	**0.01**
Congenital abnormalities	4	637	2253	2.37 (1.47 to 3.82)	**<0.001**	1.43	0.7
Caesarean section	6	1441	297 493	1.50 (1.26 to 1.79)	**<0.001**	6.39	0.27
UC *v* control							
LBW	2	1590	9410	1.66 (048 to 5.66)	0.42	4.52	**0.03**
Premature birth	6	1831	67 524	1.34 (1.09 to 1.64)	**0.005**	4.02	0.55
SGA	2	1546	9926	1.05 (0.51 to 2.16)	0.90	3.18	0.07
Caesarean section	3	204	57 780	1.30 (0.86 t o1.96)	0.21	2.49	0.29
Congenital abnormalities	2	170	1647	3.88 (1.41 to 10.67)	**0.009**	1.2	0.27
Crohn's disease *v* control							
LBW	2	597	3357	2.82 (1.42 to 5.60)	**0.003**	2.05	0.15
Premature birth	7	1005	61 565	1.97 (1.36 to 2.87)	**<0.001**	13.40	**0.04**
Still births	3	589	3558	1.91 (0.69 to 5.31)	0.22	3.12	**0.04**
SGA	2	220	1373	5.72 (0.62 to 52.81)	0.12	4.60	**0.03**
Caesarean section	4	321	57 935	1.65 (1.19 to 2.29)	**0.003**	3.77	0.29
Congenital abnormalities	3	307	1712	2.14 (0.97 to 4.74)	0.06	0.48	0.79
Crohn's disease *v* UC							
Premature birth	5	308	427	1.84 (0.78 to 4.34)	0.16	15.70	0.003
SGA	2	160	218	0.99 (0.29 to 3.35)	0.99	1.89	0.17
Caesarean section	4	230	269	1.33 (0.73 to 2.41)	0.35	4.49	0.21

HG, heterogeneity; SGA, small for gestational age; UC, ulcerative colitis.
Significant results are shown in bold.

- ✓ PRETERM BIRTH
- ✓ SGA Small for Gestational Age
- ✓ LBW Low BirthWeight
- ✓ GESTATIONAL DIABETES regardless of corticosteroid use
- ✓ PROM pre-labour rupture of membranes
- ✓ CAESAREAN SECTION (> UC)
- ✓ STILLBIRTH
- ✓ LOW APGAR SCORE

BE AWARE OF

DISEASE ACTIVITY !

A meta-analysis on the influence of inflammatory bowel disease on pregnancy

Review: Comparison of outcomes of pregnant inflammatory bowel disease (IBD) patients and non-inflammatory bowel disease
Comparison: 02 prematurity
Outcome: 07 IBD *v* control

Study or sub-category	IBD n/N	Control n/N	OR (random) 95% CI	Weight %	OR (random) 95% CI
01 all studies					
Porter RJ *et al*	13/82	12/164		6.49	2.39 (1.04 to 5.50)
Fedorkow DM *et al*	17/98	12/98		6.97	1.50 (0.68 to 3.34)
Baird DD *et al*	27/125	27/273		11.18	2.51 (1.40 to 4.49)
Kornfield D *et al*	61/756	12 741/239 017		24.72	1.56 (1.20 to 2.03)
Larzilliere P *et al*	14/150	20/339		8.35	1.64 (0.81 to 3.35)
Dominitz JA *et al*	44/262	98/1308		18.30	2.49 (1.70 to 3.66)
Bush MC *et al*	13/116	5640/56 398		11.32	1.14 (0.64 to 2.02)
Elbaz G *et al*	25/127	47/508		12.67	2.40 (1.41 to 4.09)
Subtotal (95% CI)	1716	298 105		100.00	1.87 (1.52 to 2.31)
Total events: 214 (IBD), 18 597 (control)					
Test for heterogeneity: χ^2 = 9.40, df = 7 (p = 0.23), I^2 = 25.5%					
Test for overall effect: Z = 5.83 (p< 0.001)					
02 high quality studies					
Kornfield D *et al*	61/756	12 741/239 017		45.60	1.56 (1.20 to 2.03)
Dominitz JA *et al*	44/262	93/1308		33.52	2.64 (1.79 to 3.88)
Bush MC *et al*	13/116	5460/56 398		20.88	1.18 (0.66 to 2.01)
Subtotal (95% CI)	1134	296 723		100.00	1.74 (1.14 to 2.65)
Total events: 118(IBD), 18 294 (control)					
Test for heterogenity: χ^2 = 6.88, df = 2 (p = 0.03), I^2 = 70.9%					
Test for overall effect: Z = 2.58 (p = 0.010)					
03 studies published after year 2000					
Dominitz JA *et al*	44/262	93/1308		43.10	2.64 (1.79 to 3.88)
Bush MC *et al*	13/116	5640/56 398		26.84	1.14 (0.64 to 2.02)
Elbaz G *et al*	25/127	47/508		30.06	2.40 (1.41 to 4.09)
Subtotal (95% CI)	505	58 214		100.00	1.99 (1.22 to 3.26)
Total events: 82 (IBD), 5780 (control)					
Test for heterogeneity: χ^2 = 5.95, df = 2 (p = 0.05), I^2 = 66.4%					
Test for overall effect: Z = 2.75 (p = 0.006)					
04 study group >100					
Baird DD *et al*	27/125	27/273		14.33	2.51 (1.40 to 4.49)
Kornfield D *et al*	61/756	12 471/239 017		31.67	1.59 (1.23 to 2.07)
Dominitz JA *et al*	44/262	93/1308		23.28	2.64 (1.79 to 3.88)
Bush MC *et al*	13/116	5640/56 398		14.50	1.14 (0.64 to 2.02)
Elbaz G *et al*	25/127	47/508		16.23	2.40 (1.41 to 4.09)
Subtotal (95% CI)	1386	297 504		100.00	1.95 (1.45 to 2.63)
Total events: 170 (IBD), 18 278 (control)					
Test for heterogeneity: χ^2 = 9.15, df = 4 (p = 0.06), I^2 = 56.3%					
Test for overall effect: Z = 4.39 (p<0.001)					

0.1 0.2 0.5 1 2 5 10
Favours control Favours IBD

Review Comparison of outcomes of pregnant Inflammatory bowel disease (IBD) patients and non-Inflammatory bowel disease
Comparison: 06 Mode of delivery-caesarean section
Outcome: 06 IBD *v* controls

Study or sub-category	IBD n/N	Control n/N	OR (random) 95% CI	Weight %	OR (random) 95% CI
01 all studies					
Porter RJ *et al*	17/82	17/164		3.66	2.26 (1.09 to 4.71)
Fedorkow DM *et al*	19/98	24/98		2.24	0.74 (0.38 to 1.46)
Kornfield D *et al*	115/756	24 387/239 017		49.63	1.58 (1.29 to 1.93)
Dominitz JA *et al*	73/262	254/1308		21.41	1.60 (1.18 to 2.17)
Bush MC *et al*	37/116	12 408/56 398		12.85	1.66 (1.12 to 2.45)
Elbaz G *et al*	26/127	87/508		8.21	1.25 (0.76 to 2.03)
Subtotal (95% CI)	1441	297 493		100.00	1.51 (1.27 to 1.81)
Total events:287 (IBD),37 177 (control)					
Test for heterogeneity: χ^2 = 6.48, df = 5 (p = 0.26), I^2 = 22.9%					
Test for overall effect: Z = 4.59 (p<0.001)					
02 high quality studies					
Kornfield D *et al*	11/756	24 827/239 017		59.16	1.55 (1.27 to 1.89)
Dominitz JA *et al*	73/262	254/1308		25.52	1.60 (1.18 to 2.17)
Bush MC *et al*	37/116	12 408/56 398		15.32	1.66 (1.12 to 2.45)
Subtotal (95% CI)	1134	296 723		100.00	1.58 (1.35 to 1.84)
Total events: 225 (IBD), 37 499 (control)					
Test for heterogeneity: χ^2 = 0.11, df = 2 (p = 0.94), I^2 = 0%					
Test for overall effect: Z = 5.84 (p = 0.001)					
03 studies published after 2000					
Dominitz JA *et al*	73/262	254/1308		50.41	1.60 (1.18 to 2.17)
Bush MC *et al*	37/116	12 408/56 398		30.25	1.66 (1.12 to 2.45)
Elbaz G *et al*	26/127	87/508		19.34	1.25 (0.76 to 2.03)
Subtotal (95% CI)	505	58 214		100.00	1.54 (1.24 to 1.91)
Total events: 136 (IBD), 12 749 (control)					
Test for heterogeneity: χ^2 = 0.93, df = 2 (p = 0.63), I^2 = 0%					
Test for overall effect: Z = 3.95 (p<0.001)					
04 study group>100					
Kornfield D *et al*	115/756	24 837/239 017		53.88	1.55 (1.27 to 1.89)
Dominitz JA *et al*	73/262	254/1308		23.25	1.60 (1.18 to 2.17)
Bush MC *et al*	37/116	12 408/56 398		13.95	1.66 (1.12 to 2.45)
Elbaz G *et al*	26/127	87/508		8.92	1.25 (0.76 to 2.03)
Subtotal (95% CI)	1261	297 231		100.00	1.55 (1.34 to 1.79)
Total events: 251 (IBD), 37 586 (control)					
Test for heterogeneity: χ^2 = 0.93, df = 3 (p = 0.82), I^2 = 0%					
Test for overall effect: Z = 5.84 (p<0.001)					

0.1 0.2 0.5 1 2 5 10
Control IBD

MANAGING IBD FLARES DURING PREGNANCY

J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

Joana Torres [1 2 3], María Chaparro [4], Mette Julsgaard [5 6], Konstantinos Katsanos [7], Zuzana Zelinkova [8 9], Manasi Agrawal [10 6], Sandro Ardizzone [11], Marjo Campmans-Kuijpers [12], Gabriele Dragoni [13 14], Marc Ferrante [15 16], Gionata Fiorino [17], Emma Flanagan [18], Catarina Frias Gomes [1], Ailsa Hart [19], Charlotte Rose Hedin [20 21], Pascal Juillerat [22 23], Annemarie Mulders [24], Pär Myrelid [25 26], Aoibhlinn O'Toole [27], Pauline Rivière [28], Michael Scharl [29], Christian Philipp Selinger [30 31], Elena Sonnenberg [32], Murat Toruner [33], Jantien Wieringa [34 35], C Janneke Van der Woude [36]

- ✓ MULTIDISCIPLINARY TEAM
- ✓ MANAGEMENT ACCORDING TO CURRENT GUIDELINES FOR NON-PREGNANT WOMEN (5-ASA, steroids, *ciclosporin*, anti-TNF agents, ustekinumab or vedolizumab
- ✓ AVOID thiopurine, MTX, JAK inhibitors, S1P receptors modulators
- ✓ FLARE BEYOND WEEK 37 → consider early delivery

J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

DRUG		MANAGEMENT
5-AMINOSALYCILATES	5-ASA	All preparation are now dibutyl phtalate free. CONTINUE
	Sulphasalazine	Supplementation with folate CONTINUE
CORTICOSTEROIDS	budesonide – budesonide MMX	CONTINUE
	others	WARNING maternal-fetal complication (hypertension, diabetes, preeclampsia…)
ANTIBIOTICS	metronidazole	CONTINUE
	ciprofloxacin	AVOID in T1
THIOPURINE	monotherapy	CONTINUE
	combo therapy	DISCONTINUE

J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

DRUG		MANAGEMENT
CALCINEURIN INHIBITORS	ciclosporin	LIMITED DATA
	tacrolimus	
METHOTREXATE		DISCONTINUE (counselling!)
THALIDOMIDE		DISCONTINUE (counselling!)
anti TNF		CONTINUE (if discontinued, resumption shortly)
vedolizumab		continue (LIMITED DATA)
ustekinumab / risankizumab		continue (LIMITED DATA)
Small molecules (tofacitinib, filgotinib, upadacitinib)		DISCONTINUE / CONTRAINDICATED
S1P receptors modulators (ozanimod)		DISCONTINUE / CONTRAINDICATED

anti-TNF

Gut. 2016 Aug;65(8):1261-8. doi: 10.1136/gutjnl-2015-309321. Epub 2015 May 12.

Tailored anti-TNF therapy during pregnancy in patients with IBD: maternal and fetal safety

A de Lima [1], Z Zelinkova [2], C van der Ent [1], E A P Steegers [3], C J van der Woude [1]

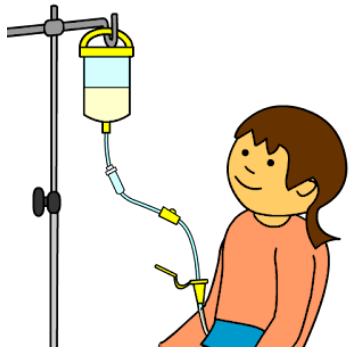
Conclusions: To limit anti-TNF exposure in utero, anti-TNF can be stopped safely in the second trimester in women with IBD in sustained remission. In patients not in sustained remission, anti-TNF may be continued without clear additional risks to the fetus. We observed excellent 1-year child outcomes compared with children from non-IBD controls.

Comparative Study Inflamm Bowel Dis. 2020 Jun 18;26(7):1110-1117. doi: 10.1093/ibd/izz250.

Early Discontinuation of Infliximab in Pregnant Women With Inflammatory Bowel Disease

Brindusa Truta [1], Ira L Leeds [1 2], Joseph K Canner [2], Jonathan E Efron [2], Sandy H Fang [2], Azah Althumari [1], Bashar Safar [2]

Conclusions: Steroid-free remission IBD mothers are at risk for disease flares and preterm babies when IFX is discontinued early in pregnancy. Continuation of IFX seems to be safe at least for the first year of life.



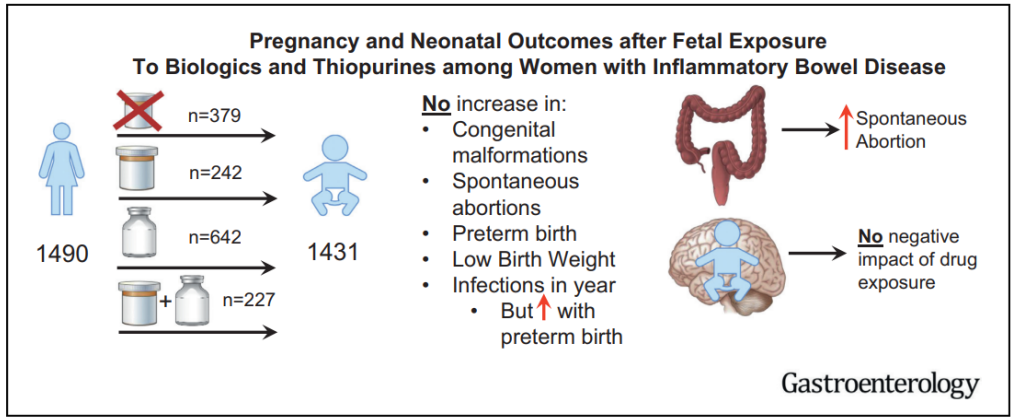
Neonatal Outcomes After Fetal Exposure to Biologics and Thiopurines among women with IBD

PIANO Study

Pregnancy in Inflammatory Bowel Disease and Neonatal Outcomes

Prospective, observational, multicenter USA study, from 2007 to 2019

Event	Overall	No Exposure (n=379)	Biologics (n=642)	Thiopurine (n=242)	Combination (n=227)	p
Any Pregnancy Complications (%) [excluding IUGR^, Cesarean Section or Preterm Delivery] *	280 / 1,389 (20)	66 / 352 (19)	127 / 600 (21)	52 / 226 (23)	35 / 211 (17)	0.30
Spontaneous Abortion (%)	42 / 1,485 (3)	10 / 378 (3)	19 / 640 (3)	7 / 242 (3)	6 / 225 (3)	0.99
Preterm Birth [<37 weeks] (%)	132 / 1,364 (10)	33 / 343 (10)	43 / 594 (7)	28 / 221 (13)	28 / 206 (14)	0.02
Small for Gestational Age (%)	58 / 1,353 (4)	15 / 340 (4)	31 / 588 (5)	5 / 221 (2)	7 / 204 (5)	0.26
Low Birth Weight [<2500 g] (%)	91 / 1,367 (7)	24 / 342 (7)	39 / 594 (7)	12/ 225 (5)	16 / 206 (8)	0.77
Intrauterine Growth Restriction (%)	30 / 1,489 (2)	10 / 378 (3)	13 / 642 (2)	2 / 242 (1)	5 / 227 (2)	0.47
Cesarean Section (%)	611 / 1,376 (44)	135 / 345 (39)	268 / 598 (45)	102 / 226 (45)	106 / 207 (51)	0.05
Neonatal ICU at Birth (%)	137 / 1,383 (10)	32 / 348 (9)	57 / 600 (10)	23 / 227 (10)	25 / 208 (12)	0.71
Any Congenital Malformations (%)	126 / 1,394 (9)	26 / 354 (7)	57 / 606 (9)	22 / 224 (10)	21 / 210 (10)	0.63



*From questionnaires and medical records. Exposure was defined as use of thiopurines or biologic in the 3 months before last menstrual period or any time during pregnancy

Mahadevan et al, Gastroenterology 2020

Observational Study > J Crohns Colitis. 2022 Dec 5;16(12):1808-1815.
doi: 10.1093/ecco-jcc/jjac086.

Safety of Ustekinumab and Vedolizumab During Pregnancy–Pregnancy, Neonatal, and Infant Outcome: A Prospective Multicentre Study

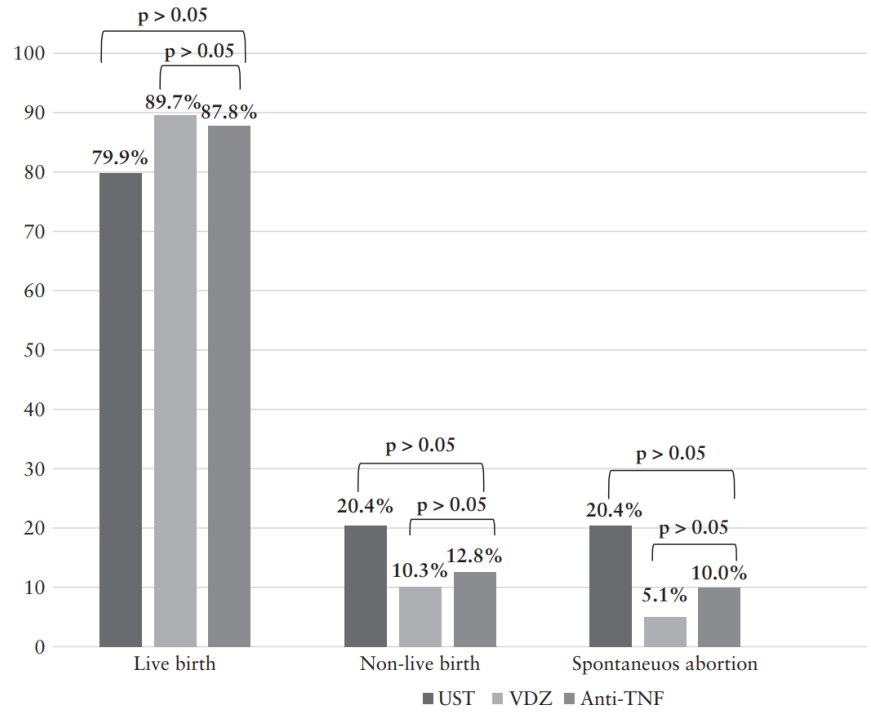
Katarina Mitrova [1 2], Barbora Pipek [3 4 5], Martin Bortlik [6 7 8], Ludek Bouchner [9], Jan Brezina [10], Tomas Douda [11], Tomas Drasar [12], Pavel Klvana [13], Pavel Kohout [14], Vaclav Leksa [15], Petra Minarikova [8], Ales Novotny [16], Pavel Svoboda [5], Jan Skorpik [17], Jan Ulbrych [18 19], Marek Veinfurt [20], Blanka Zborilova [20], Milan Lukas [1], Dana Duricova [1 7]; Czech IBD Working Group

Table 2 Newborn outcome.

	Ustekinumab *n* = 43	Vedolizumab *n* = 35	Anti-TNF *n* = 79	*p*-value UST vs anti-TNF	*p*-value VDZ vs anti-TNF
Preterm birth [%]	1 [2.3]	3 [8.6]	5 [6.3]	0.423	0.699
Gestational age at birth[a]	39 [35–41]	39 [26–41]	39 [31–42]	0.246	0.249
Caesarean section [%]	25 [58.1]	19 [54.3]	38 [48.1]	0.289	0.685
Biologics, last application [g.w.][a]	33 [18–38][b]	33 [18–38][b]	30 [22–39]	0.008	0.090
Birthweight [g][a]	3250 [2240–4230]	3098 [650–3780]	3291 [1435–4170]	0.391	0.134
Low birthweight [%]	3 [7.0]	4 [11.4]	4 [5.1]		
Low birthweight [%] [Term deliveries only]	3 [7.0]	1 [3.1]	0		
Apgar score <7 [%]	1 [2.3]	1 [2.9]	2 [2.5]	1.00	1.00
Perinatal complications [%]	2 [4.7]	3 [8.6]	7 [8.9]	0.491	1.00
Icterus with phototherapy	1	1	5		
Bronchopneumonia	-	1	-		
RDS + sepsis [*E. coli*]	-	1	1		
Congenital toxoplasmosis	1	-	-		
Umbilical infection [*Staphylococcus* sp.]	-	-	1		
Congenital malformation [%]	3 [7.0]	2 [5.7]	2 [2.5]	0.344	0.585

Pregnancies exposed to:

- ✓ Ustekinumab 54
- ✓ Vedolizumab 39
- ✓ Anti TNF 70



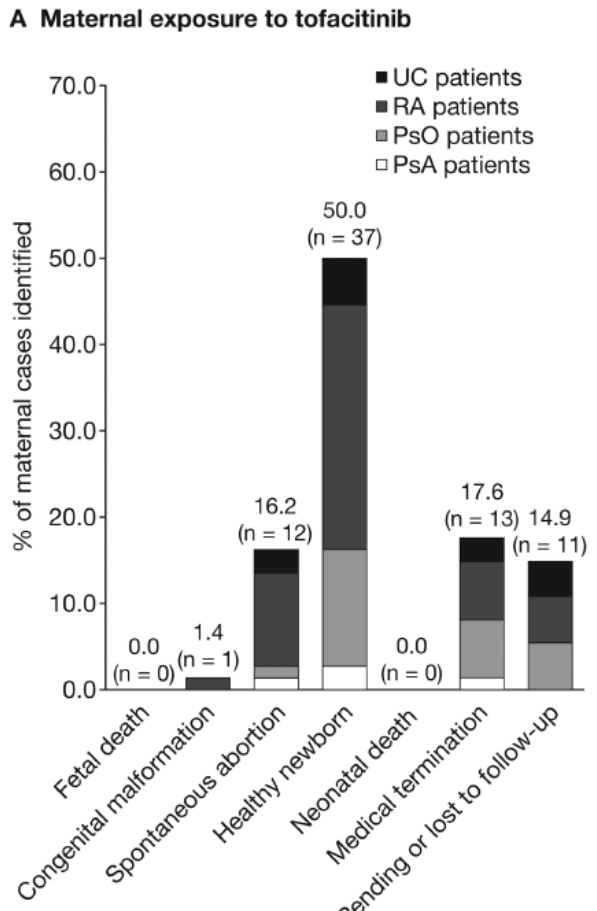
anti jak and PREGNANCY

In animal studies, tofacitinib was feticidal and teratogenic in rats and rabbits (exposures many times greater than the standard human dose).

TABLE 3: Pregnancy Outcomes in Cases of Maternal or Paternal Exposure Identified in the Tofacitinib UC Intervention Studies

Cases of Exposure	Maternal Exposure to Tofacitinib (n = 11), No. (% of Identified Cases)	Paternal Exposure to Tofacitinib (n = 14), No. (% of Identified Cases)
Healthy newborn[a]	4 (36.4)	11 (78.6)
Medical termination[b]	2 (18.2)	0 (0.0)
Neonatal death	0 (0.0)	0 (0.0)
Fetal death	0 (0.0)	0 (0.0)
Congenital malformation	0 (0.0)	0 (0.0)
Spontaneous abortion	2 (18.2)	0 (0.0)
Pending or lost to follow-up	3 (27.3)	3 (21.4)

[a]Includes 1 preterm birth (36 weeks, 2.92 kg).
[b]Case #1: the patient decided to terminate the pregnancy based on the potential risks of tofacitinib. Case #2: reason unknown.



Mahadevan et al IBD 2018

Reported outcomes of pregnancy cases identified from tofacitinib RCT, post-approval and non-interventional studies, and spontaneous adverse-event reporting appear similar to those observed in the general population.
At present, the use of tofacitinib during pregnancy should be avoided.

MODE OF DELIVERY

"Natural childbirth is not prohibited"

Torres J, JCC 2022

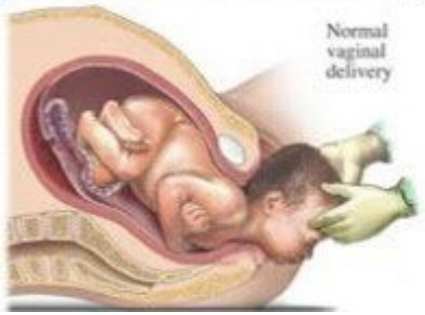
Statement 29

The mode of delivery does not seem to influence outcome of patients with IBD regarding development or worsening of inactive perianal disease [EL2] and anal sphincter damage [EL2]

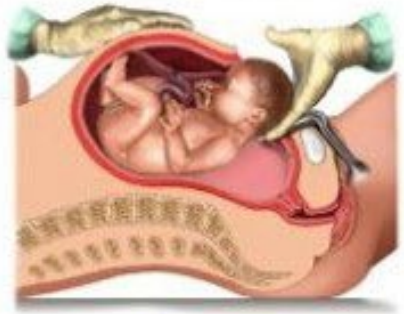
Statement 30

Mode of delivery should be guided by obstetric considerations. In patients with active perianal disease, prior rectovaginal fistula, and after restorative proctocolectomy, C-section is recommended after multidisciplinary discussion involving gastroenterologists, obstetricians, and IBD surgeons [EL5]

Vaginal Delivery



Cesarean Delivery



- ✓ RISK OF POSTPARTUM FLARE
- ✓ BREASTFEEDING WITH IBD
- ✓ VACCINATIONS

RISK OF POSTPARTUM FLARE

- ✓ relapse postpartum rate 25-50% (UC > CD)
- ✓ predictors
    - disease activity during T3
    - therapy de-escalation during and after pregnancy
    - longer duration of disease (> CD)
- ✓ if discontinued, resumed the treatment asap

BREASTFEEDING

> J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

DRUG		MANAGEMENT
5-AMINOSALYCILATES	5-ASA	LOW RISK
	Sulphasalazine	LOW RISK
CORTICOSTEROIDS	budesonide – budesonide MMX	LOW RISK
	others	LOW RISK
ANTIBIOTICS	metronidazole	AVOID
	ciprofloxacin	LOW RISK (short-term, alternatives?)
THIOPURINE		LOW RISK

BREASTFEEDING

> J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

DRUG		MANAGEMENT
CALCINEURIN INHIBITORS	ciclosporin	LIMITED DATA
	tacrolimus	
METHOTREXATE		AVOID
THALIDOMIDE		AVOID
anti TNF		LOW RISK
vedolizumab / ustekinumab / risankizumab		LOW RISK (LIMITED DATA)
Small molecules (tofacitinib, filgotinib, upadacitinib)		AVOID (NO DATA)
S1P receptors modulators (ozanimod)		AVOID (NO DATA)

VACCINATIONS

J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

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Statement 34

Inactivated vaccines are recommended according to national guidelines. In children exposed *in utero* to biologics, live attenuated vaccines should be withheld within the first year of life or until the biologic is no longer detectable in the infant's blood [EL3]

TAKE HOME MESSAGES

- ✓ conception and pregnancy are important life events
- ✓ a concomitant diagnosis of IBD brings additional layer of concern and anxiety
- ✓ counseling
- ✓ monitoring
- ✓ disease activity

PRE

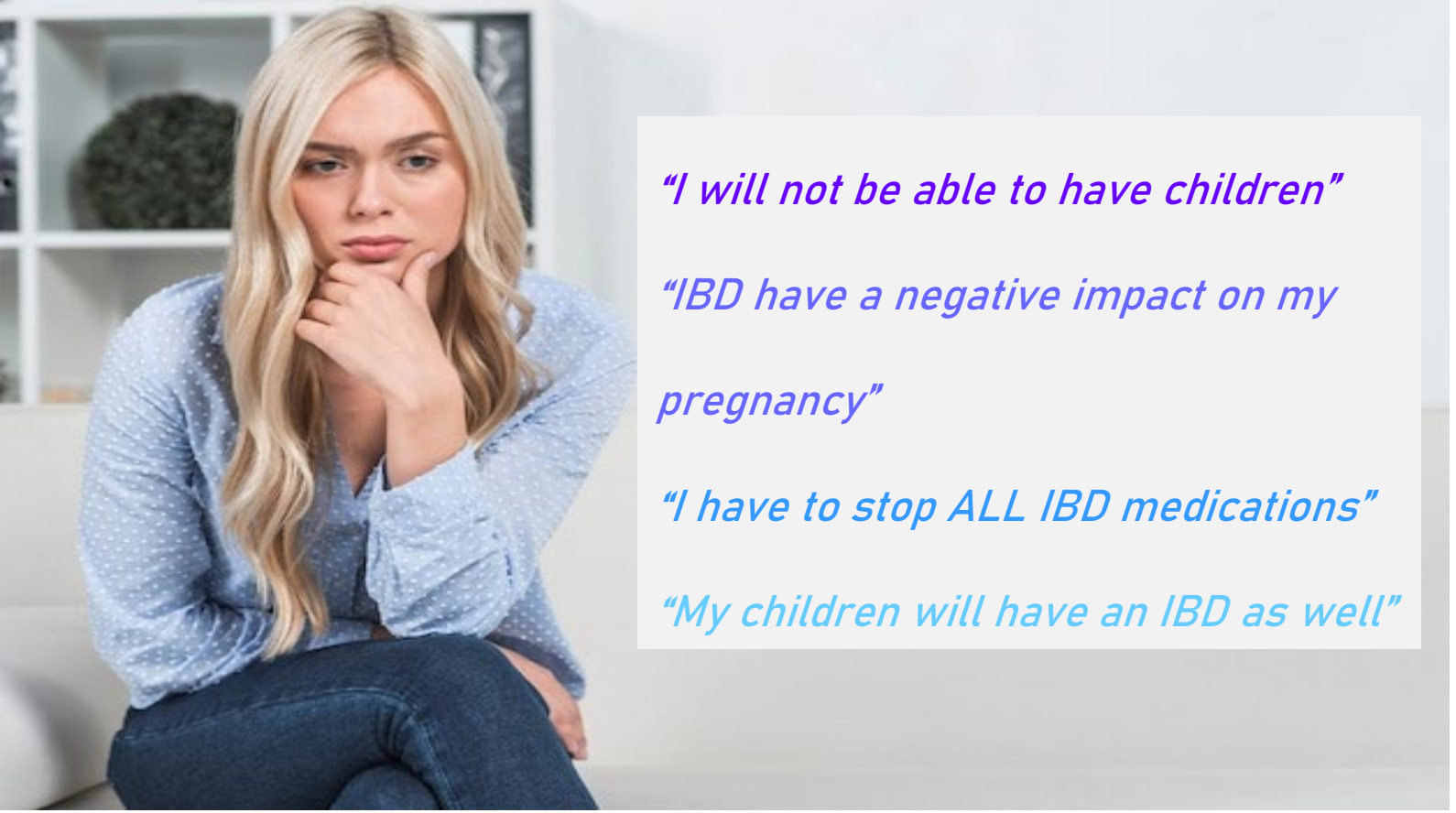
DURING

POST

I care.

I always care.


Thank you



"I will not be able to have children"

"IBD have a negative impact on my pregnancy"

"I have to stop ALL IBD medications"

"My children will have an IBD as well"

ECCO GUIDELINES ON SEXUALITY, FERTILITY, PREGNANCY AND LACTATION

J. Torres et al JCC 2023 17, 1 – 27

1

BEFORE PREGNANCY

- Discuss disease heritability
- Smoking, alcohol and recreational drug cessation
- Ensure cervical cancer screening and vaccinations are updated
- Screen for anemia and vitamin deficiencies
- Folic acid prescription
- Review safety of drugs during pregnancy: stop methotrexate, Jak inhibitors, and ozanimod before conception, and consider alternative therapy to ensure good disease control
- Assess disease activity, optimize treatment to ensure disease remission
- Establish an individualized plan with the patient for disease monitoring and management during pregnancy
- Discuss risk/benefit of drug maintenance during pregnancy and lactation

"The exams for IBD monitoring can cause problems for the baby"

"Colonoscopy is forbidden"

"Now the priority is the child and not the activity of my illness"

"I will have to give birth with a caesarean"

ECCO GUIDELINES ON SEXUALITY, FERTILITY, PREGNANCY AND LACTATION

J. Torres et al JCC 2023 17, 1 – 27

2

DURING PREGNANCY

- Discuss risk/benefit of drug maintenance during pregnancy
- Establish a plan for delivery and mode of delivery
- Monitor with faecal calprotectin and intestinal ultrasound if available
- Monitor for adequate weight gain during pregnancy
- Discuss risk/benefit of drug maintenance during lactation
- Discuss safety of vaccination in the children
- Discuss management plan with family doctor and/or obstetrician

"I can't breastfeed"

"what about vaccines?"

"I feel alone with my child

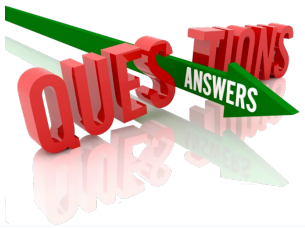
and my illness"

ECCO GUIDELINES ON SEXUALITY, FERTILITY, PREGNANCY AND LACTATION

J. Torres et al JCC 2023 17, 1 – 27

AFTER DELIVERY

- Promptly restart treatment in women that stopped therapy during pregnancy
- Discuss safety of drugs during lactation
- Postpone live vaccines during the first 6–12 months of life in children exposed to biologics in utero, or until levels in children are undetectable
- Screen for mental health problems in the post-partum period



IBD and PREGNANCY
(IN DREAMLAND ?)

Disease management

- 3-month steroid-free remission prior to conception
- Confirm remission with endoscopy or other objective markers

Medication management

- Stop methotrexate ≥ 3 months prior to conception
- Continue mesalamine
  - Sulfasalazine requires 2 mg folic acid daily
- Taper off corticosteriods
- Continue azathioprine monotherapy
- Continue biologic therapy
  - Measure serum drug levels
  - Consider risk/benefit of stopping concomitant azathioprine
- Tofacitinib: avoid or use with caution

PRECONCEPTION

Healthcare maintenance

- Up-to-date Papanicolaou smear
- Vaccines
- Cessation of drugs, alcohol and tobacco
- Taper off opioids
- Colon cancer surveillance
- Achieve healthy weight
- Start a prenatal vitamin
- Standard preconception health care (as per ACOG guidelines[121])
- Effective contraception (LARC)

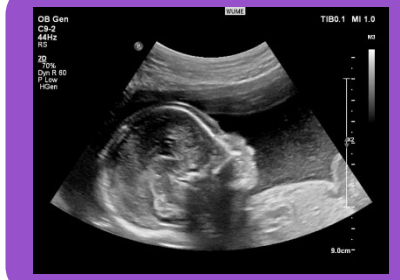
MULTIDISCIPLINARY TEAM

- ✓ gastroenterologist
- ✓ gynecologist
- ✓ obstetrician
- ✓ paediatrician
- ✓ psycologist
- ✓ nutrinionist
- ✓ surgeon
- ✓ lactation counselor

Interdisciplinary consultation

- Nutrition: ensure adequate caloric intake and vitamin levels
- MFM: history of prior pregnancy complication
- Colorectal surgeon: history of IPAA or ostomy

MONITORING



Monitoring of pregnancy

Monitoring of IBD
(disease and medications)

Monitoring of nutrition and weight gain

Monitoring - *when?*

IBD Remission

- ✓ GI visit every trimester and as needed
- ✓ complete blood test and FCP every visit

IBD Flare

- ✓ GI follow-up every 2 weeks
- ✓ adjust medication
- ✓ monitor labs and FCP
- ✓ strumental evaluation

Maternal/fetal monitoring

- ✓ Gyn and obstetrician visit and growth ultrasound based on national guideline
- ✓ counseling on delivery

Maternal/fetal monitoring

- ✓ fetal growth surveillance every 4 weeks
- ✓ US cervical lenght screening (18-22 wks)
- ✓ nutrition counseling
- ✓ Pt on steroids should have early glucose screen
- ✓ Counseling on delivery

Mahadevan et al Gastroenterology 2019

Review > Gut. 2007 Jun;56(6):830-7. doi: 10.1136/gut.2006.108324. Epub 2006 Dec 21.

A meta-analysis on the influence of inflammatory bowel disease on pregnancy

J Cornish [1], E Tan, J Teare, T G Teoh, R Rai, S K Clark, P P Tekkis

Table 2 Pregnancy outcomes in inflammatory bowel disease versus controls

Outcome of interest	No of studies	Patients with IBD (n)	Controls (n)	OR (95% CI)	p Value	HG χ^2	HG p value
IBD *v* Control							
LBW	3	1033	239 864	2.10 (1.38 to 3.19)	**<0.001**	3.87	0.14
Premature birth	8	1716	298 105	1.87 (1.52 to 2.31)	**<0.001**	9.4	0.23
SGA	4	1097	240 931	1.87 (0.61 to 5.7)	0.27	52.36	**<0.001**
Still births	4	1243	240 931	1.48 (0.89 to 2.47)	0.13	11.43	**0.01**
Congenital abnormalities	4	637	2253	2.37 (1.47 to 3.82)	**<0.001**	1.43	0.7
Caesarean section	6	1441	297 493	1.50 (1.26 to 1.79)	**<0.001**	6.39	0.27
UC *v* control							
LBW	2	1590	9410	1.66 (048 to 5.66)	0.42	4.52	**0.03**
Premature birth	6	1831	67 524	1.34 (1.09 to 1.64)	**0.005**	4.02	0.55
SGA	2	1546	9926	1.05 (0.51 to 2.16)	0.90	3.18	0.07
Caesarean section	3	204	57 780	1.30 (0.86 t o1.96)	0.21	2.49	0.29
Congenital abnormalities	2	170	1647	3.88 (1.41 to 10.67)	**0.009**	1.2	0.27
Crohn's disease *v* control							
LBW	2	597	3357	2.82 (1.42 to 5.60)	**0.003**	2.05	0.15
Premature birth	7	1005	61 565	1.97 (1.36 to 2.87)	**<0.001**	13.40	**0.04**
Still births	3	589	3558	1.91 (0.69 to 5.31)	0.22	3.12	**0.04**
SGA	2	220	1373	5.72 (0.62 to 52.81)	0.12	4.60	**0.03**
Caesarean section	4	321	57 935	1.65 (1.19 to 2.29)	**0.003**	3.77	0.29
Congenital abnormalities	3	307	1712	2.14 (0.97 to 4.74)	0.06	0.48	0.79
Crohn's disease *v* UC							
Premature birth	5	308	427	1.84 (0.78 to 4.34)	0.16	15.70	0.003
SGA	2	160	218	0.99 (0.29 to 3.35)	0.99	1.89	0.17
Caesarean section	4	230	269	1.33 (0.73 to 2.41)	0.35	4.49	0.21

HG, heterogeneity; SGA, small for gestational age; UC, ulcerative colitis.
Significant results are shown in bold.

- ✓ PRETERM BIRTH
- ✓ SGA Small for Gestational Age
- ✓ LBW Low BirthWeight
- ✓ GESTATIONAL DIABETES regardless of corticosteroid use
- ✓ PROM pre-labour rupture of membranes
- ✓ CAESAREAN SECTION (> UC)
- ✓ STILLBIRTH
- ✓ LOW APGAR SCORE

BE AWARE OF

DISEASE ACTIVITY !

MANAGING IBD FLARES DURING PREGNANCY

J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

Joana Torres [1 2 3], María Chaparro [4], Mette Julsgaard [5 6], Konstantinos Katsanos [7], Zuzana Zelinkova [8 9], Manasi Agrawal [10 6], Sandro Ardizzone [11], Marjo Campmans-Kuijpers [12], Gabriele Dragoni [13 14], Marc Ferrante [15 16], Gionata Fiorino [17], Emma Flanagan [18], Catarina Frias Gomes [1], Ailsa Hart [19], Charlotte Rose Hedin [20 21], Pascal Juillerat [22 23], Annemarie Mulders [24], Pär Myrelid [25 26], Aoibhlinn O'Toole [27], Pauline Rivière [28], Michael Scharl [29], Christian Philipp Selinger [30 31], Elena Sonnenberg [32], Murat Toruner [33], Jantien Wieringa [34 35], C Janneke Van der Woude [36]

- ✓ MULTIDISCIPLINARY TEAM
- ✓ MANAGEMENT ACCORDING TO CURRENT GUIDELINES FOR NON-PREGNANT WOMEN (5-ASA, steroids, *ciclosporin*, anti-TNF agents, ustekinumab or vedolizumab
- ✓ AVOID thiopurine, MTX, JAK inhibitors, S1P receptors modulators
- ✓ FLARE BEYOND WEEK 37 → consider early delivery

anti-TNF

Gut. 2016 Aug;65(8):1261-8. doi: 10.1136/gutjnl-2015-309321. Epub 2015 May 12.

Tailored anti-TNF therapy during pregnancy in patients with IBD: maternal and fetal safety

A de Lima [1], Z Zelinkova [2], C van der Ent [1], E A P Steegers [3], C J van der Woude [1]

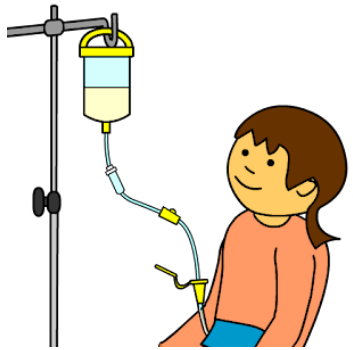
Conclusions: To limit anti-TNF exposure in utero, anti-TNF can be stopped safely in the second trimester in women with IBD in sustained remission. In patients not in sustained remission, anti-TNF may be continued without clear additional risks to the fetus. We observed excellent 1-year child outcomes compared with children from non-IBD controls.

Comparative Study Inflamm Bowel Dis. 2020 Jun 18;26(7):1110-1117. doi: 10.1093/ibd/izz250.

Early Discontinuation of Infliximab in Pregnant Women With Inflammatory Bowel Disease

Brindusa Truta [1], Ira L Leeds [1 2], Joseph K Canner [2], Jonathan E Efron [2], Sandy H Fang [2], Azah Althumari [1], Bashar Safar [2]

Conclusions: Steroid-free remission IBD mothers are at risk for disease flares and preterm babies when IFX is discontinued early in pregnancy. Continuation of IFX seems to be safe at least for the first year of life.



VACCINATIONS

J Crohns Colitis. 2023 Jan 27;17(1):1-27. doi: 10.1093/ecco-jcc/jjac115.

European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation

Joana Torres [1 2 3], María Chaparro [4], Mette Julsgaard [5 6], Konstantinos Katsanos [7], Zuzana Zelinkova [8 9], Manasi Agrawal [10 6], Sandro Ardizzone [11], Marjo Campmans-Kuijpers [12], Gabriele Dragoni [13 14], Marc Ferrante [15 16], Gionata Fiorino [17], Emma Flanagan [18], Catarina Frias Gomes [1], Ailsa Hart [19], Charlotte Rose Hedin [20 21], Pascal Juillerat [22 23], Annemarie Mulders [24], Pär Myrelid [25 26], Aoibhlinn O'Toole [27], Pauline Rivière [28], Michael Scharl [29], Christian Philipp Selinger [30 31], Elena Sonnenberg [32], Murat Toruner [33], Jantien Wieringa [34 35], C Janneke Van der Woude [36]

Statement 34

Inactivated vaccines are recommended according to national guidelines. In children exposed *in utero* to biologics, live attenuated vaccines should be withheld within the first year of life or until the biologic is no longer detectable in the infant's blood [EL3]