

Long-Term Safety of In Utero Exposure to Anti-TNF α Drugs for the Treatment of Inflammatory Bowel Disease: Results from the Multicenter European TEDDY Study

Retrospective long-term cohort study of children born to women with IBD on antiTNF during pregnancy

- **Aim:** to compare the RR of severe infections
- **Secondary aims:** To compare the prevalence of malformations of children exposed to antiTNF compared to those non exposed.
- To compare the prevalence of neoplasm in children exposed to antiTNF and to ascertain the RR of complications

Results:

N: 841

- **Severe infections** in non-exposed vs exposed children 1.6% vs. 2.8% p-y, HR 1.2 (0.8–1.8), p=ns.
- No differences in: overall proportion of complications 14.9% exposed vs 17.7%; p=0.29
- Proportion of **infections in mothers** treated with antiTNF was higher 4.1% vs 0.9%; p=0.002
- **Complications during delivery** higher in exposed cohort 57.5% vs 43.5%; p<0.01
- Children admitted to **intensive care** unit higher in exposed 7% vs 3.1%; p<0.01
- **Low birth weight** higher in exposed 9.8% vs 5%; p<0.01
- No differences in malformations
- **Preterm birth** associated with risk of **severe infection** after birth p<0.001

Conclusions:

In utero exposure to anti-TNF drugs does not seem to be associated with increased short-term or long-term risk of severe infections in children.

Table 5. Factors associated with the risk of severe infection in offspring during follow-up

	Hazard ratio	95% confidence interval	P
Exposed (vs. non-exposed)	1.2	0.8–1.8	0.3
Preterm delivery	2.9	1.5–5.5	0.001
Low birth weight	0.7	0.3–1.6	0.4

Table 3. Prevalence of complications during pregnancy and delivery and complications affecting newborn's complications

	Exposed cohort N=388	Non-exposed cohort N=453	P
<i>Complications during pregnancy (%)</i>	14.9	17.7	0.29
Growth retardation	3.4	2.9	0.68
Infection	4.1	0.9	0.002
Eclampsia	1.3	0.9	0.5
Placenta previa	0.5	0.4	0.8
Chorioamnionitis	0.3	0.4	0.6
Abruptio placenta	5.2	6	0.61
<i>Delivery-related complications (%)^a</i>	57	43	0.001
Instrumental delivery	11.6	7.7	0.05
Cesarean section	43.8	32	0.001
Preterm delivery	10.6	7.3	0.09
<i>Newborn complications (%)</i>	24.5	16	0.002
Congenital malformations	5.4	2.6	0.06
Intensive care unit admission	7	3.1	0.009
Low birth weight	10.6	6.8	0.05
Low Apgar score	14.7	11.5	0.16

^aDelivery-related complications excluding cesarean section: 20.4% exposed cohort vs. 14.6% non-exposed cohort (P=0.02).

