Safety of IBD drugs during pregnancy and breasfeeding: mothers and babies' outcomes (DUMBO 2 registry)

First published: 18/12/2025

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000887

Study ID

1000000887

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Inflammatory bowel disease (IBD)—including Crohn’s disease, ulcerative colitis, and indeterminate or unclassifiable colitis—is a condition characterized by inflammation of the intestine of unknown cause. IBD is often diagnosed during the reproductive years; therefore, it is important for physicians caring for these patients to be able to adequately address questions regarding the potential risks that medications used to treat IBD may pose to the child’s development. In general, most drugs used to treat IBD, such as corticosteroids or aminosalicylates, are not associated with risks to the child. However, the safety of administering other medications during pregnancy is more controversial. In particular, the safety of newer biologic agents (mainly vedolizumab, ustekinumab, risankizumab, mirikizumab, and guselkumab, among others) and small molecules (tofacitinib, filgotinib, upadacitinib, ozanimod, and etrasimod) has been little studied.
Through the present study, we aim to assess pregnancy outcomes and the development of children up to 4 years of age according to the medications received by the mother.

STUDY DESIGN:
This is an observational, multicenter, non-interventional study evaluating the safety of newly approved treatments for IBD during pregnancy, breastfeeding, and the first 4 years of the child’s life.

OBJECTIVES:
Primary objective:
To evaluate the safety of new treatments used to treat IBD (non–anti-TNF therapies and small molecules) during pregnancy and the first 4 years of the newborn’s life, focusing on the risk of developing severe infections.

Secondary objectives:
To determine the risk of serious adverse events during pregnancy and delivery

associated with new therapies used to treat IBD.
To evaluate the development of children born to mothers exposed to new treatments during the first 4 years of life.
To compare the relative risk of serious adverse events in children born to mothers exposed in utero to new treatments with that of children not.

Study status

Finalised

Research institutions and networks

Institutions

Hospital Universitario de La Princesa

Grupo Español de Trabajo en Enfermedad de Crohn y Colitis Ulcerosa (GETECCU)

Contact details

Study institution contact

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Study timelines

Date when funding contract was signed
Planned: 15/04/2024

Actual: 15/04/2024

Study start date
Planned: 15/04/2024

Actual: 15/04/2024

Date of final study report
Planned: 15/04/2034

Actual: 17/12/2025

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

NCT06337565

NCT03894228

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Study design:

This is an observational, multicenter, non-interventional study evaluating the safety of newly approved treatments for IBD during pregnancy, breastfeeding,

and the first 4 years of the child’s life.

Main study objective:

To evaluate the safety of new treatments used to treat IBD (non–anti-TNF therapies and small molecules) during pregnancy and the first 4 years of the newborn’s life, focusing on the risk of developing severe infections.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

This study will include pregnant patients receiving any of the newly approved treatments for IBD (ustekinumab, vedolizumab, mirikizumab, risankizumab, guselkumab, tofacitinib, filgotinib y upadacitinib)

Special population of interest

Nursing women

Pregnant women

Documents

Study publications

https://pubmed.ncbi.nlm.nih.gov/40518059/

https://pubmed.ncbi.nlm.nih.gov/34158835/

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after creation of study variables