Ustekinumab and Risk of Small for Gestational Age in Inflammatory Bowel Disease Pregnancies: Data from the DUMBO Registry

First published: 02/06/2026

Last updated: 11/06/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000001012

Study ID

1000001012

DARWIN EU® study

No

Study countries

Spain

Study description

This study is a retrospective observational cohort analysis based on data extracted from the DUMBO registry (Safety Of IB(D) Dr(U)gs During Pregnancy And Breastfeeding: (M)others and (B)abies' (O)utcomes), a prospective Spanish multicenter registry designed to evaluate maternal and neonatal outcomes in women with inflammatory bowel disease (IBD) exposed to IBD therapies during pregnancy. The objective of the study is to compare the incidence rates of small for gestational age (SGA) infants born to women with IBD exposed to ustekinumab (including biosimilars) during pregnancy to those exposed to anti-tumor necrosis factor alpha (TNFα) agents (infliximab, adalimumab, golimumab, including biosimilars) or to immunomodulators (including corticosteroids) or to either biologics or immunomodulators.

Study status

Finalised

Research institutions and networks

Institutions

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

Contact details

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Study timelines

Date when funding contract was signed

Actual: 03/03/2026

Study start date

Actual: 01/05/2019

Data analysis start date

Actual: 03/03/2026

Date of final study report

Planned: 15/05/2026

Actual: 19/05/2026

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

REDACTED_Protocol-FD-PCSIMMA0309-1776580_1921577.pdf (942.91 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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)

Data collection methods:

Secondary use of data

Study design:

Observational design, based on analysis of data from the DUMBO registry, a prospective Spanish cohort of pregnant women with IBD supported by Grupo Español de Trabajo en Enfermedad de Crohn y Colitis Ulcerosa (GETECCU)

Main study objective:

To assess whether exposure to ustekinumab (and biosimilars) during pregnancy in women with inflammatory bowel disease (IBD) is associated with an increased risk of small for gestational age (SGA) infants compared to those exposed to anti-tumor necrosis factor (TNFα) agents (infliximab, adalimumab, golimumab, including biosimilars), immunomodulators and to those not exposed to either biologics or immunomodulators.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

STELARA

Study drug International non-proprietary name (INN) or common name

USTEKINUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC05) ustekinumab

ustekinumab

Medical condition to be studied

Inflammatory bowel disease

Population studied

Short description of the study population

9.2.2.1. Inclusion Criteria

The population under study will consist of women meeting the following criteria:

 Pregnant women with confirmed IBD (CD, UC, IBD-U) recruited into the DUMBO registry before week 28 of gestation.

 Exposed to mesalazine, immunomodulators including corticosteroids, anti-TNFα agents, ustekinumab or not exposed to any treatment at any time during pregnancy or 3 months prior to conception;

9.2.2.2. Exclusion Criteria

Women who meet any of the following criteria will not be eligible for this study:

 Patients exposed to known teratogens from conception through the first trimester of pregnancy (Gomes 2021).

 Patients exposed to targeted small molecules (eg. JAKi, S1P modulators), or biologics other than anti-TNFα agents or ustekinumab

 Lack of informed consent, or loss to follow-up prior to delivery.

Age groups

- Adults (18 to < 65 years)

Special population of interest

Pregnant women

Special population of interest, other

Pregnant women with IBD

Estimated number of subjects

954

Study design details

Setting

DUMBO (Safety Of IB(D) Dr(U)gs During Pregnancy And Breastfeeding (M)others And (B)abies' (O)utcomes) registry database.

Comparators

exposure to anti-TNFα agents (primary comparator)
exposure to immunomodulators or no immunomodulatory/biologic therapy (secondary comparators)

Outcomes

The primary outcome is to assess small for gestational age (SGA). SGA is defined as birth weight below the 10th percentile for gestational age and sex. For term newborns (greater than or equal to [>=] 37 weeks) world health organization (WHO) growth standards will be used; for preterm infants (less than [<] 37 weeks) Fenton growth charts will be applied. Maternal demographic and clinical data (disease characteristics, activity and treatment) will be extracted at baseline.

Data analysis plan

Descriptive analysis will include baseline characteristics of mothers of live-born infants which will be described for each exposure group using means and standard deviations (SD) or medians and interquartile ranges (IQR) for continuous variables, and frequencies (%) for categorical variables. Comparison of baseline characteristics between exposure groups will be performed to characterize differences before propensity score (PS) weighting. A description of the planned statistical methods to be used to analyze the data collected. The report will include descriptive data of the number of mothers of life-born infants who have entered the study in each of the treatment cohorts, trimester of exposure and counts and proportion of infants with SGA tabulated by exposure status at cohort entry. The associations between maternal characteristics and SGA will be assessed by univariate analysis. And to minimize confounding by indication multivariable analysis will be applied in order to achieve covariate balance between groups.

Summary results

Results: A total of 954 pregnancies with 980 live births were included in the analysis. The overall incidence of SGA was 11%, and the proportion of infants classified as SGA was similar across treatment groups (37 cases [11%] in the non- treated group, 27 [11%] in the immunomodulator group, 37 [12%] in the anti-TNFα group, and 10 [11%] in the ustekinumab group). In multivariable analysis, ustekinumab exposure was not associated with an increased risk of SGA compared with anti-TNFα therapy, immunomodulators including corticosteroids, or no immunosuppressive treatment : compared with ustekinumab exposure, adjusted OR (95% CI) were: 1.17 (0.53–2.78) for immunomodulators/corticosteroids, 1.37 (0.65–3.16) for anti-TNFα therapy, and 1.37 (0.61
3.33) for no immunosuppressive therapy. Independent predictors of SGA included female infant
sex, and disease activity during pregnancy (higher risk of SGA).

Conclusions: In this prospective cohort of pregnancies in women with IBD, exposure to ustekinumab during pregnancy was not associated with an increased risk of SGA infants compared with other treatment groups. These findings provide reassuring real-world evidence regarding the fetal growth safety profile of ustekinumab in pregnancy.

Documents

Study report

20260609_PCSIMMA0309_CTIS Redacted CSR_Synopsis_English_Disclaimer_Updated.pdf (335.44 KB)

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.

Data sources

Data source(s), other

DUMBO Registry

Data sources (types)

Disease registry

Pregnancy registry

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

Unknown