Tofacitinib Pregnancy Exposure Registry OTIS Autoimmune Diseases in Pregnancy Project (OTIS PASS Tofacitinib)

First published: 30/01/2014
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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/46130

EU PAS number
EUPAS5703

Study ID
46130

DARWIN EU® study
No

Study countries
United States

Study description
The Tofacitinib Pregnancy Exposure Registry is a United States-based registry designed to monitor planned or unplanned pregnancies exposed to tofacitinib when used to treat rheumatoid arthritis.

Study status
Ongoing

Research institution and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

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Institution

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Andrea Leapley

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
31/07/2013
Actual:
17/06/2013

Study start date
Planned:
31/08/2013
Actual:
01/11/2013

Date of final study report
Planned:
30/03/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

Study protocol

A3921203_PROTOCOL_23DEC2013_2.pdf(942.37 KB)

A3921203_PROTOCOL AMENDMENT 1_V2.0_24JUN2019 .doc.pdf(1.82 MB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Main study objective:
The main objective of the study is to conduct an observational cohort study that will involve follow-up of live born infrants to one year of age to assess the potential increase in the risk of birth defects in pregnancies exposed to tofacitinib compared with an unexposed comparator population.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Xeljanz

Medical condition to be studied
Rheumatoid arthritis
Psoriatic arthropathy
Colitis ulcerative

Population studied

Age groups
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)

Special population of interest
Pregnant women

Estimated number of subjects
300

Study design details

Outcomes
The primary outcome variable is major structural defects. Secondary outcomes include: minor structural defects, spontaneous abortions, stillbirth, premature delivery, small for gestational age, postnatal growth deficiency, loss to follow-up, serious or opportunistic infections and malignancies.

Data analysis plan
The primary analysis for the cohort study will be a comparison of the birth prevalence of major structural defects in live born infants between the tofacitinib-exposed group and the primary comparator group. This analysis will use chi-square or Fisher's Exact test for univariate comparisons and logistic regression or Cochran-Mantel-Haenzsel test for multivariate analysis (ie, adjustment of possible confounders including demographics and disease duration).

Data management

Data sources

Data sources (types)
Disease registry

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No