Evaluation of the risks of biologic drugs exposure during pregnancy in patients with rheumatic chronic inflammatory diseases: data from the French national healthcare data system (SNDS) (BIOGRIC)

First published: 02/09/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS31199

Study ID

44499

DARWIN EU® study

No

Study countries

☐ France

Study description

Rheumatoid arthritis (RA) psoriatic arthritis (PsoA) and Spondyloarthritis (SpA) are the most frequent rheumatic chronic inflammatory disease (RCID) in women of childbearing age, and can lead to permanent joint destruction and disability. Biologics, in particular TNF inhibitors (TNFi), have dramatically improved the outcome of these patients, nevertheless, an increased infectious risk related to these drugs has been reported. The main aim of this study is to compare the risks of a 'poor pregnancy outcome' in exposed vs not exposed to TNFi RCID patients. Secondary aims are: a) To describe the treatment of RA, SpA or PsoA during pregnancy regarding: • Non-steroidal-anti-inflammatory drugs and corticosteroids, • Conventional disease-modifying anti-rheumatic drugs (DMARDs), • Biologic DMARDs: TNFi and other biologics. b) To compare, in women with RA, SpA or PsoA exposed to TNFi vs unexposed women, the risks of maternal and perinatal infections, congenital malformations and gestational diabetes c) To evaluate the risk of above-described outcomes in pregnant patients exposed to other biologics during pregnancy in RA, SpA or PsoA women.

Study status

Ongoing

Research institutions and networks

Institutions

Assistance Publique - Hôpitaux de Paris (AP-HP)

France

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Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

Florence TUBACH florence.tubach@aphp.fr

Study contact

florence.tubach@aphp.fr

Primary lead investigator

Anna Molto

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2019

Actual: 01/01/2019

Study start date

Planned: 31/12/2019

Actual: 24/09/2019

Data analysis start date

Planned: 31/12/2019

Actual: 24/09/2019

Date of final study report
Planned: 31/12/2022

Sources of funding

- Other

More details on funding

French Ministry of Health

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To compare the risks of poor pregnancy outcomes in patients with RA, SpA or PsoA exposed to TNFi versus unexposed patients with RA, SpA or PsoA.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors

Tumor necrosis factor alpha (TNF-alpha) inhibitors

Medical condition to be studied

Rheumatoid arthritis

Psoriatic arthropathy

Spondylitis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

84100

Study design details

Outcomes

Poor pregnancy outcome: intrauterine growth restriction, therapeutic abortion, stillbirth (death of a fetus with a gestational age ≥ 22 weeks or birth weight > 500gr), preterm delivery, perinatal mortality, maternal hospitalization due to infection, small for gestational age (birth weight < 3th percentile) or hospitalization in neonatal intensive care unit at 37 weeks. - Treatment during pregnancy: NSAID, corticoids, conventional and biologic DMARDS - All the individual items of the composite main outcome - Severe and non-severe maternal infections, severe perinatal infections of the offspring, severe infections of the offspring the first year of life, severe congenital malformations, gestational diabetes, spontaneous and elective abortions, preterm delivery.

Data analysis plan

The main analysis focuses on the comparison of event risk between women exposed to TNFi and women not exposed to biologics (therefore pregnancies that are exposed to another biologic than a TNFi will be excluded from this analysis). Event rates will be compared by a logistic model. To account for the fact that exposed women are likely to be different from unexposed women, a

propensity score will be constructed using both pregnancy-related variables and underlying rheumatologic disease variables.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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