The Mycophenolate Pregnancy Registry

First published: 15/07/2016

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27036

EU PAS number

EUPAS10541

Study ID

27036

DARWIN EU® study

No

Study countries

☐ United States

Study description

The Mycophenolate Pregnancy Registry is designed as a prospective, observational registry collecting data regarding mycophenolate exposure during pregnancy, and pregnancy, fetal and infant outcomes after exposure. Early and later term pregnancy outcomes will be solicited at selected gestational time points and at the estimated date of delivery. Structural and functional birth defects identified in the perinatal period through one year of life will be collected and classified.

Study status

Ongoing

Research institutions and networks

Institutions

Campbell Alliance

First published: 01/02/2024

Last updated: 01/02/2024

Institution

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Trial Information Support Line TISL

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Annette Stemhagen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/02/2009

Study start date

Actual: 20/11/2012

Date of final study report

Planned: 31/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genentech, Inc. Novartis Pharma. Corp. Accord Healthcare, Inc. Alkem Lab. Ltd. Alkem Lab.Ltd. U.S. REMS Agent Apotex Corp. Mylan Pharma., Inc. Pfizer, Inc. Roxane Lab., Inc. Sandoz Incorporated Teva Pharma. USA, Inc. Vintage Pharma., LLC

Study protocol

MPR-ML22679_Protocol_version_6.pdf(1.18 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

ML22679

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Voluntary reporting by HCPs and/or patients of any mycophenolate-exposed pregnancy in the US.

Main study objective:

• Document maternal and fetal outcomes of each exposed pregnancy to further characterize the risk of mycophenolate fetal exposure. • Determine mycophenolate exposure status for each reported pregnancy.• Root cause analysis of circumstances that led to fetal exposure.• Identify factors that affect the risk of adverse outcomes such as dose, timing of exposure, or maternal characteristics.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

A prospective, observational registry

Study drug and medical condition

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

MYCOPHENOLATE MOFETIL

MYCOPHENOLIC ACID

Medical condition to be studied

Pregnancy

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

• Maternal outcomes: Incidence of pregnancy complications• Fetal outcomes: Incidence of congenital disorders• Time/duration of mycophenolate exposure•

Mycophenolate dose/regimen• Indications for mycophenolate use• Maternal medical/demographic characteristics, • Occurrence of educational counseling on the risks of birth defects with mycophenolate therapy

Data analysis plan

All statistical analyses will be coordinated by Outcome Sciences, Inc. Analyses and reporting will be performed semi-annually, for regulatory update or other purposes, and possibly more often according to the needs of and at the discretion of the Registry sponsor(s) and the Mycophenolate Pregnancy. Based on the prospective case data, 95% confidence intervals will be constructed around the observed defect rate. For pregnancies with known outcome, line listings and descriptive summaries will be included.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Exposure 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