The Mycophenolate Pregnancy Registry

First published: 15/07/2016

Last updated: 15/04/2026

Study Ongoing

Administrative details

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

global.clinical_trial_registry@roche.com

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: 31/12/2040

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genentech, Inc., Novartis Pharmaceuticals Corporation, Accord Healthcare, Inc., Alkem Lab. Ltd. Alkem Lab.Ltd. U.S. REMS Agent, Amneal Pharmaceuticals, Amta Labs Limited, Apotex Corp., Avet Lifesciences Limited, Azurity Pharmaceuticals, Inc., Biocon Pharma Limited, Concord Biotech Limited, Endo Pharmaceuticals, Inc., Hetero Labs Limited, Hikma Pharmaceuticals USA Inc., Hisun Pharmaceuticals, Jubilant Cadista Pharmaceuticals Inc., Lannett Company, Inc., Meitheal Pharmaceuticals, Inc., Mylan Pharmaceuticals Inc., Rising Pharma Holdings, Inc., RK Pharma Inc., Sandoz Incorporated, Strides Pharma, Inc., Teva Pharmaceuticals USA, Inc., TWi Pharmaceuticals, Inc., VistaPharm, Inc., Wuxi Fortune Pharmaceutical Co., Ltd, Zydus Pharmaceuticals

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 topic:

Human medicinal product

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.

Data collection methods:

Primary data collection

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.
• Understand the circumstances that led to fetal exposure (pregnancy root cause analysis).
• 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

Medicinal product name

CELLCEPT

MYFORTIC

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

MYCOPHENOLATE MOFETIL

MYCOPHENOLIC ACID

Anatomical Therapeutic Chemical (ATC) code

(L04AA06) mycophenolic acid

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

• Overall pregnancy outcome (spontaneous losses/miscarriages, live births, fetal deaths, and elective terminations)
• Any adverse fetal outcomes or birth defects that may be attributable to pregnancy exposure to mycophenolate
• Duration of mycophenolate exposure (peri-conception and by gestational period)
• Mycophenolate product dose and regimen
• Indication for mycophenolate product use
• Maternal medical/demographic characteristics
• Root cause analysis: intended vs. unintended pregancies, contraception use, and education (occurrence of educational counseling on the risks of birth defects with mycophenolate therapy)
• Gestational age at completion or termination of the pregnancy
• Pregnancy complications and fetal outcomes, including birth defects, birth weight and length and neurodevelopmental status
• In spontaneous losses, elective terminations and stillbirths, any birth defects identified prenatally or reported based on pathology reports

Data analysis plan

All statistical 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 birth defect rate. For pregnancies with known outcome, line listings and descriptive summaries will be included.

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 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