

A non-interventional post-authorization safety study (NI-PASS) of outcomes associated with the use of tacrolimus around conception, or during pregnancy or lactation using data from Transplant Pregnancy Registry International (TPRI)

First published: 22/12/2021

Last updated: 22/09/2025

Study

Finalised

Administrative details

EU PAS number

EUPAS37025

Study ID

47431

DARWIN EU® study

No

Study countries

Study description

The primary purpose of this study was to estimate prevalence of major malformations (as a combined group) among children born to female transplant recipients using tacrolimus-containing-regimens (or alternative immunosuppressants, as a combined group) during the period from 6 weeks prior to conception to the end of the first trimester without use of mycophenolic acid (MPA).

Similarly, for minor malformations (as a combined group).

This study also described the distribution of types of malformations among children born to female transplant recipients using tacrolimus (or alternative immunosuppressants as a combined group).

Additional objectives evaluated prevalence of spontaneous abortions, still births, small for gestational age, gestational diabetes mellitus, gestational hypertension and pre-eclampsia.

TRPI is based in the United States and includes self-reported data from individuals from any country based on a minimum set of criteria.

Study status

Finalised

Contact details

Study institution contact

Clinical Trial Registration

clinicaltrialregistration@astellas.com

[Study contact](#)

clinicaltrialregistration@astellas.com

Primary lead investigator

Michael Moritz

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/03/2020

Actual: 05/03/2020

Study start date

Planned: 10/01/2022

Actual: 03/01/2022

Data analysis start date

Planned: 03/01/2022

Actual: 03/01/2022

Date of final study report

Planned: 30/06/2023

Actual: 03/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe B.V.

Study protocol

[Astellas-tacrolimus F506-PV-0001 Protocol V 3.0 9JUL2021-Disclosure-Redacted.pdf](#) (5.09 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

F506-PV-0001

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To estimate prevalence of major malformations (as a combined group), among livebirth children born to female transplant recipients using tacrolimus-containing-regimens (or alternative immunosuppressants, as a combined group) during the period from 6 weeks prior to conception to the end of the first trimester without use of mycophenolic acid (MPA). Similarly, for minor malformations (as a combined group).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Tacrolimus

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

Anatomical Therapeutic Chemical (ATC) code

(L04AD02) tacrolimus

tacrolimus

Population studied

Short description of the study population

The study population consisted of transplant recipients in a defined tacrolimus-exposed group, as well as a defined alternative immunosuppressant group identified from the transplant pregnancy registry international (TPRI), from initial marketing of tacrolimus in the United States (1994) until 31 December 2020.

Age groups

- Preterm newborn infants (0 - 27 days)
 - Term newborn infants (0 - 27 days)
 - Infants and toddlers (28 days - 23 months)
 - Children (2 to < 12 years)
 - Adults (18 to < 46 years)
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Special population of interest

Pregnant women

Estimated number of subjects

3515

Study design details

Outcomes

Newborn outcomes: major and minor malformations, small for gestational age/intrauterine growth retardation (SGA/IUGR). Pregnancy outcomes: live births, spontaneous abortions, still births. Maternal outcomes: gestational diabetes mellitus (GDM), gestational hypertension (GH), pre-eclampsia.

Data analysis plan

This is a descriptive study and provides estimates together with confidence intervals for the defined outcomes in the different groups.

Documents

Study report

[Tacrolimus_F506-PV-0001_CSR draft v2.0 22Nov2024-Disclosure-Redacted.pdf](#)
(3.53 MB)

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)

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