Cidofovir Exposure Registry Study (CERS)

First published: 15/01/2020

Last updated: 10/12/2024

Study Finalised

Administrative details

EU PAS number

EUPAS33124

Study ID

48580

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

EMA requested Tillomed to conduct a PASS of Cidofovir to identify the indications and patient populations for the use of Cidofovir, as well as to evaluate patterns and compare rates of adverse events occurring in the on label group with events occurring in the off label group, and to assess the patient outcome following treatment in the specified indication. Countries involved in this joint PASS are the United Kingdom, Germany, Belgium and Spain.

Study status

Finalised

Contact details

Study institution contact

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Study contact

Sorina.Paiu@tillomed.com

Primary lead investigator

Sorina-Liana Paiu

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/12/2016

Actual: 06/03/2017

Study start date

Planned: 03/07/2017

Actual: 14/08/2019

Date of final study report

Planned: 30/11/2024

Actual: 30/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Tillomed Laboratories Ltd

Study protocol

Cidofovir PASS Protocol V1.pdf (549.81 KB)

Protocol Version 2.0_Cidofovir PASS - Redacted.pdf (942.05 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

DE/H/6139/001/DC

Methodological aspects

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 identify the indications and patient populations for the use of Cidofovir, as well as to evaluate patterns and compare rates of adverse events occurring in the on label group with events occurring in the off label group, and to assess the patient outcome following treatment in the specified indication.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, multi-centre, multi-national, study

Study drug and medical condition

Medicinal product name, other

Cidofovir 75 mg/ml concentrate for solution for infusion, Cidofovir Tillomed 75 mg/ml Konzentrat zur Herstellung einer Infusionslösung, Cidofovir Tillomed 75 mg/ml concentrado para solución para perfusión EFG, Cidofovir Tillomed 75 mg/ml concentraat voor oplossing voor infusie Cidofovir Tillomed 75 mg/ml solution à diluer pour perfusion

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

CIDOFOVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AB12) cidofovir

cidofovir

Population studied

Short description of the study population

Patients prescribed with cidofovir identified from the European countries, including the UK, Belgium, Germany, and Spain for the study period of June 2016 to June 2018.

Inclusion criteria:

• The patient is exposed to Cidofovir (Emcure’s formulation);

• Patient or patient’s authorised carer (in event the patient is unable to consent) is willing to provide written informed consent;

• The patient should have reported exposure or outcomes which are verified by a HCP. Any reported exposure or outcome not verified by a HCP, should exclude the patient from the Cidofovir Exposure Registry.

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)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

2951

Study design details

Data analysis plan

Patients prescribed Cidofovir for on-label or off label indication will be recorded and monitored to observe frequency of adverse events in the on-label group versus the off-label group. This information will be recorded via a website that the marketing authorisation holder will implement and information can be extracted to analyse these data sets.

Documents

Study report

cidofovir final pass annual report 2024_Redacted.pdf (140.64 KB)

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

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