An open label, registry study of the safety of ILUVIEN® 190 micrograms intravitreal implant in applicator (IRISS)

First published: 20/09/2016

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15411

Study ID

41077

DARWIN EU® study

No

Study countries

Germany

Portugal

United Kingdom

Study description

This study will assess the safety in patients treated with ILUVIEN. The specific objectives include the study of known safety risks of cataract formation or progression, increased intraocular pressure (both within 30 minutes post-treatment and long-term), changes in intraocular pressure and development of glaucoma, procedural complications such as endophthalmitis, retinal tears, retinal detachments, vitreous haemorrhage or vitreous detachments. Potential safety risks that have not been observed in clinical trials will also be monitored such as, retinitis secondary to reactivation of latent viral infections or other ophthalmic infections, potential systemic events associated with the use of corticosteroids or haemorrhagic events associated with the concurrent therapy with anticoagulant medications. Unknown safety risks will be captured as well. Information on significant retinal ischaemia, removal of the implant, long-term safety data, and repeat use will be evaluated. An evaluation of safety in patients who have received ILUVIEN in both eyes during the study will also be performed. Any use in paediatric patients, pregnant or lactating women and off-label use for other retinal oedema conditions will be reported. It should be understood that the sponsor does not advocate the use of ILUVIEN for any indication other than that which is specified on the Summary of Product Characteristics. However, it is also known that, in clinical practice with marketed products, off-label use is common. Therefore, the sponsor intends to collect safety data for any patient treated with ILUVIEN. Finally, the effect of ILUVIEN on visual acuity will be examined.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacovigilance and Pharmacoepidemiology, AIBILI

Portugal

First published: 11/04/2011

Last updated: 01/09/2023

Institution **Educational Institution** **Not-for-profit** **ENCePP partner**

Pharmacovigilance and Pharmacoepidemiology, AIBILI

Portugal

First published: 11/04/2011

Last updated: 01/09/2023

Institution **Educational Institution** **Not-for-profit** **ENCePP partner**

Networks

European Vision Institute Clinical Research Network (EVICR.net)

Austria

Belgium

Denmark

France
Germany
Greece
Ireland
Italy
Netherlands
Portugal
Slovakia
Spain
Switzerland
United Kingdom (Northern Ireland)

First published: 07/03/2022

Last updated: 23/02/2023

Network ENCePP partner

CRN NIHR

Contact details

Study institution contact

Ashley Gantt ashley.gantt@alimerasciences.com

Study contact

ashley.gantt@alimerasciences.com

Primary lead investigator

Usha Chakravarthy

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/03/2013

Actual: 31/03/2013

Study start date
Planned: 10/04/2014

Actual: 10/04/2014

Data analysis start date
Planned: 14/02/2020

Date of final study report
Planned: 13/05/2021

Actual: 13/05/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alimera Sciences Limited

Study protocol

M-01-12-001 Consolidated Protocol - Amendments 1 and 2 PDF.pdf (258.44 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)

Other study registration identification numbers and links

NCT01998412

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

This study will assess the safety in patients treated with ILUVIEN. The specific objectives include the study of known safety risks, potential safety risks not observed in clinical trials, unknown safety risks, significant retinal ischaemia, removal of the implant, long-term safety data and repeat use and evaluation of safety in patients who have received ILUVIEN in both eyes.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-randomized, open label, uncontrolled, multi-centre, safety study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(S01BA15) fluocinolone acetonide

fluocinolone acetonide

Medical condition to be studied

Macular oedema

Population studied

Short description of the study population

Any patient treated with ILUVIEN may be included in the study.
Patients/Guardians who are unable to understand and sign the Informed Consent Form will be excluded from the study.

Retrospective Enrolment Criteria:
Patients treated with ILUVIEN prior to study initiation may be included provided they satisfy the inclusion and exclusion criteria, where applicable, as well as, the following requirements:
1. The site is allowed to enrol a patient who was treated with ILUVIEN no more than 36 months prior to bringing the patient in for their first study visit.
2. The eligible patient must meet the data requirements as specified in the protocol, i.e., baseline data collected within 7 days prior to treatment with ILUVIEN and additional data subsequently collected approximately every 6 months thereafter until enrolment into the study.
3. The eligible patient must be enrolled at least one year prior to the planned end of the study.

Age groups

- 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)

Estimated number of subjects

550

Study design details

Data analysis plan

A sample size of 550 patients will provide approximately 80% probability of detecting one or more reports of any adverse event with a true underlying 5-year incidence of 0.3% assuming a 0.050 2-sided significance level. Data from all patients receiving an ILUVIEN implant will be included in the analyses of safety. Safety in specific subgroups, e.g. pregnant or lactating women and paediatric patients, will be evaluated. Formal study reports of analyses of study data will be performed at 3 years and 5 years. Analyses will also be conducted using preliminary data on an "as-needed" basis for marketing purposes and for Periodic Safety Update Reports. Safety analyses will be conducted to enumerate the number of patients with ocular and systemic adverse events, significant intraocular pressure related and cataract-related events, receiving retreatment, and undergoing implant explantation. Changes from baseline intraocular pressure and best corrected visual acuity will be summarized.

Documents

Study results

m-01-12-001-6y-synop.pdf (50.09 KB)

Study publications

Chakravarthy U, Taylor SR, Koch FH, de Sousa JP, Bailey C. Changes in intraocul...

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, Retrospective patient-based data collection

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