Cyclosporine 1mg/ml eye drop emulsion (Ikervis®) for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes: Clinical effectiveness, tolerability and safety in a real world setting.

First published: 22/01/2018

Last updated: 22/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS22376

Study ID

36178

DARWIN EU® study

No

Study countries

Finland

Germany

Norway

Sweden

United Kingdom

Study description

This is a prospective, non-interventional study of the effectiveness, tolerability and safety of Ikervis® in the targeted population as defined in section 1.6 of the SPC, in a real world setting

Study status

Ongoing

Research institutions and networks

Institutions

Universitätsklinikum Tübingen

First published: 01/02/2024

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Institution

Augenklinik

Hyks silmaklinikka Helsinki, Paijat-Hameen Keskussairaala (PHKS) (Paijat-Hame Central Hospital) Lahti, Augenklinik des Universitatsklinikums Wurzburg Wurzburg, Chiemsee Augentagesklinik Prien, Augenklinik des Universitatsklinikums Magdeburg Magdeburg, Universitaetsklinikum Des Saarlandes Und Medizinische Fakultaet Der Universitaet Des Saarlandes Homburg, MVZ Schweinfurt Schweinfurt, Universitats-Augenklinik Freiburg Freiburg, Universitatsklinikums Hamburg Eppendorf Hamburg, Augenklinik des Universitatsklinikums Tubingen Tubingen

Contact details

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Study contact

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Primary lead investigator

Manfred Zierhut

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2016

Actual: 01/09/2016

Study start date

Planned: 19/05/2017

Actual: 19/05/2017

Data analysis start date

Planned: 25/10/2019

Date of final study report

Planned: 07/01/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANTEN

Study protocol

IKERVIS Protocol.pdf (753.34 KB)

Amended Protocol V3_04Apr2018_ Clean_ Eng_Final.pdf (863.47 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

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

Tolerability and safety in a real world setting

Main study objective:

The primary objective of this study is to assess the effectiveness of Ikervis® in controlling severe keratitis, as measured by corneal fluorescein staining (CFS) improvement from baseline to 12 months (± 45 days) from treatment initiation, in patients who have not improved despite treatment with tear substitutes, in routine clinical practice

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

Medicinal product name

IKERVIS

Medical condition to be studied

Dry eye

Population studied

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

400

Study design details

Outcomes

The primary endpoint is change in the grade of corneal fluorescein staining (CFS) from baseline to 12 months from initiation of Ikervis® treatment.baseline value will be collected and shall be measured only after obtaining informed consent and within 7 days before the start of Ikervis® treatment. Endpoint data will be collected 12 months (± 45 days) from the initiation of Ikervis® treatment. • To assess the following– foreign body sensation– burning/stinging– itching– pain– sticky feeling– blurred vision– photophobia• To assess tear production using Schirmer’s test• To assess tear film breakup time (TFBUT)• To evaluate eyelid and conjunctival erythema• Quantify reductions in the use of artificial tears• To quantify steroid tapering

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Data analysis plan

Statistical analysis:The unit of analysis will be patient’s worst eye which will be identified as the eye with the worst CFS score at baseline if both of a patient’s eyes are treated. If both eyes have the same CFS score then data from the right eye will be used. If only one eye is treated, then that eye will be the unit of study, irrespective of whether or not it was the worst eye at baseline.The primary endpoint analysis will be a comparison of the CFS score at baseline and at 12 months after Ikervis® treatment start. CFS score at baseline and at 12

months post Ikervis® initiation will be assessed as continuous variable as well as categorical variable based on oxford grading scale. CFS as categorical variable, as well as change in CFS after 12 months of treatment, will be summarized by their mode as these are ordinal variables, as well as by number and percentage of each.

Documents

Study, other information

sites final 0240-0023.pdf (42.57 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

Prospective 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