Long-term safety after Holoclar® implant for restoration of corneal epithelium in patients with limbal stem cell deficiency due to ocular burns: observational study of routine clinical practice (HOLOSIGHT)

First published: 06/07/2015

Last updated: 27/08/2020

Study Ongoing

Administrative details

EU PAS number

EUPAS10043

Study ID

36923

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium

- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] United Kingdom

Study description

This observational, prospective, study aims to evaluate the long-term safety profile of patients treated with Holoclar® during a 5-year follow-up period from first ocular implantation under routine clinical conditions, through the description of the occurrence of adverse events, adverse drug reactions, serious adverse events and adverse events of special interest.

Study status

Ongoing

Research institutions and networks

Institutions

Holostem Terapie Avanzate Srl

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Fania Ferrari

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/05/2015

Actual: 05/05/2015

Study start date

Planned: 20/09/2016

Actual: 20/10/2016

Data analysis start date

Planned: 01/03/2027

Date of final study report

Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Holostem Terapie Avanzate Srl

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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Other

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

Effectiveness of risk minimization measures

Main study objective:

To evaluate the long-term safety profile of patients treated with Holoclar during a 5-year follow-up period from first ocular implantation under routine clinical conditions

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

HOLOCLAR

Medical condition to be studied

Limbal stem cell deficiency

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

100

Study design details

Outcomes

Safety outcomes (AEs and symptoms) will be collected from biopsy to end of observation.AEs include Serious and Non-serious Adverse Events, Adverse Drug Reactions and Adverse Events of Special Interest (AESI). AESI are defined as glaucoma and blepharitis.Symptoms include pain, photophobia, burning, Quality of life, rate of success, visual acuity during 5 years

Data analysis plan

Analyses will include data collected at available observational points, according to clinical practice and clinical judgment. For vital signs, LSCD severity, symptoms, corneal epithelium defects, superficial corneal neovascularization and BCVA at corneal biopsy, if the evaluation is not performed on the same day, the most recent available data at the time will be collected instead. In order to summarize data by time point (e.g. one year after implant, two years after implant, etc.), the nearest available evaluation/ measurement will be considered.Concerning the safety profile, the proportion of patients experiencing at least one adverse event, serious adverse event, AE related to biopsy, surgical procedure, post-implant pharmacological treatment or cell-based product and AESI will be provided, both globally and for the 5 years observational period from the first implantation. The occurrence of symptoms will be described too.

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)

Disease registry

Spontaneous reports of suspected adverse drug reactions

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring, Surgery 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