Post-market clinical follow-up study – Retrospective evaluation of endothelial cell density and IOL explants related to the clinical use of AcrySof® CACHET® Phakic Lens in three European countries

First published: 07/02/2014

Last updated: 13/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/14318

EU PAS number

EUPAS5584

Study ID

14318

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Spain

Study description

This is a post-market clinical follow-up study to evaluate endothelial cell density (ECD) and intraocular lens explants related to the clinical use of AcrySof® CACHET® Phakic Lens, for the correction of myopia, in three European countries: Spain, France and Germany. Phakic anterior chamber implants are used for the correction of myopia or hypermetropia. Loss of endothelial cells of the cornea may cause clouding of the cornea and blurred vision, in some cases leading to explants.This study aims to capture data on ECD in a real-life setting and to quantify the frequency of ECL and AcrySof® CACHET® Phakic Lens explants. This study has a retrospective cohort design. It will include patients implanted with AcrySof® CACHET® Phakic Lens between 2008 and 2013. Sites from Germany, Spain, and France will be selected. In each country, a lead investigator will be recruited to centralize and help organize the research effort in the country. Information from patient medical records will be collected through an online electronic data capture platform (one file per implanted eye), and preoperative (demographics, ECD measurements, among others) and postoperative (ECD measurements and explants information) data will be abstracted. The mean and standard deviation of ECD at the last preoperative visit and each month after surgery will be provided. Counts and percentages, with the corresponding 95% confidence intervals, of the following outcomes will be provided: acute ECL, chronic ECL, explants of AcrySof® CACHET® Phakic Lens ≤ 6 months after implant, and explants of AcrySof® CACHET® Phakic Lens > 6 months of implant.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom
- ☐ United Kingdom (Northern Ireland)
- ☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Kantar Health

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Kantar Health GmbH Germany, Clinics France, Clinics Germany, Clinics Spain

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2013

Actual: 22/07/2013

Study start date

Planned: 15/06/2014

Actual: 22/07/2014

Data analysis start date

Planned: 01/11/2014

Actual: 27/11/2014

Date of final study report

Planned: 08/05/2015

Actual: 21/05/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alcon Labs, Inc.

Study protocol

Cachet Protocol Redacted.pdf(286.68 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Medical device

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary goals of the study are to capture data on endothelial cell density in a real-life setting and to quantify the frequency of endothelial cell loss and AcrySof® CACHET® Phakic Lens explants.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Patients implanted with AcrySof® CACHET® Phakic Lens between 2008 and 2013.

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

200

Study design details

Outcomes

1) Acute ECL (detected ≤ 6 months after implant)- ECD < 1,500 cells/mm2- ECL > 30% of preoperative value2) Chronic ECL (thresholds as above, detected > 6 months of implant)3) Explant of the AcrySof® CACHET® Phakic Lens ≤ months after implant

Data analysis plan

The main outcome will be the Frequency of endothelial cell loss (ECL) and explants. Kaplan-Meier estimates of cumulative endothelial cell loss (ECL) will be provided as graphics. Point estimates of the proportion of subjects who experienced the outcome at months 3 and 12 with 95% confidence intervals will be provided. To incorporate the variance correlation expected in the data, we will implement marginal regression models for correlated responses. We plan to create two different sets of models: one with a binary outcome, ECL, and the other with a continuous outcome, ECD. Depending on the number of explants, a third model can be built to explore the risk factors for this binary outcome, These models will be used to estimate the probability of ECL (model 1), the ECD (model 2) and of explants (if model 3 is built) per month.The unit of analysis will be operated eyes.

Documents

Study results

RTI-HS_Alcon Cachet Study_EU_PAS_SummaryResults Repag.pdf(56.23 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Information will be collected from patient medical records through an online electronic data capture platform specifically constructed for the use of the treating surgeons.

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