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

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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 institution 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 19/02/2024

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

Study institution contact
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Alejandro Arana
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 data collection

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

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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