Acute effects of intravitreal aflibercept injections on intraocular pressure in vitrectomized and silicone-oil-filled eyes (NH_SiOP)

First published: 06/11/2025

Last updated: 06/11/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000811

Study ID

1000000811

DARWIN EU® study

No

Study countries

Hungary

Study description

A prospective, single-center, single-blind interventional cohort study was conducted from March 2022 to February 2025. After obtaining informed consent, patients requiring IVA were enrolled in one of the three study arms and analyzed. The G-SiO group included previously vitrectomized eyes that had undergone SiO tamponade (Oxane 1300, Bausch & Lomb, Bridgewater, NJ, USA). The G-PPV group consisted of previously vitrectomized eyes with 23G pars plana vitrectomy (PPV) surgery performed more than 3 months before enrollment, did not have SiO tamponade, or had undergone prior SiO tamponade. The G-NVIT group included eyes with intact vitreous bodies. Being treatment-naïve to IVIs was not a prerequisite for participating in the trial, whereas all participants' eyes were treatment-naïve to antiglaucoma medications (not even temporary IOP lowering treatment was administered following SiO implantation or PPV surgery) and showed no signs of glaucomatous optic nerve disease.
The Ethics Committee of the University of Szeged reviewed and approved the trial (Protocol no. NH_SiOP-001, Reference no. 168/2022-SZTE RKEB). The study was conducted in accordance with the tenets of the Declaration of Helsinki.
If both eyes were eligible, both were enrolled in the study, as the treatment method did not differ among the cohorts.

Study status

Finalised

Research institutions and networks

Institutions

Department of Ophthalmology, University of Szeged

Contact details

Study institution contact

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Study timelines

Date when funding contract was signed

Actual: 01/03/2022

Study start date

Actual: 01/03/2022

Data analysis start date

Actual: 03/03/2025

Date of final study report
Actual: 03/03/2025

Sources of funding

- No external funding

Study protocol

NH_SiOP Protocol.pdf (126.19 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 topic:

Medical procedure

Study type:

Clinical trial

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This study is designed as a prospective, single-center, single-blind interventional cohort trial. Patients requiring intravitreal aflibercept were enrolled in one of the three study arms (silicone oil, vitrectomized or unaltered) and analyzed.

Main study objective:

To assess and compare acute intraocular pressure (IOP) changes following intravitreal aflibercept injections in vitrectomized eyes with and without silicone oil tamponade and in nonvitrectomized eyes.

Study Design

Clinical trial regulatory scope

Post-authorisation interventional clinical trial

Clinical trial phase

Therapeutic use (Phase IV)

Clinical trial randomisation

Non-randomised clinical trial

Clinical trial types

Pragmatic clinical trial

Study drug and medical condition

Medicinal product name

EYLEA

Study drug International non-proprietary name (INN) or common name

AFLIBERCEPT

Anatomical Therapeutic Chemical (ATC) code

(S01LA05) aflibercept

aflibercept

Medical condition to be studied

Macular oedema

Retinal vein occlusion

Neovascular age-related macular degeneration

Vitrectomy

Population studied

Short description of the study population

Patients requiring intravitreal aflibercept are enrolled in one of the three study arms and analyzed. The G-SiO group includes previously vitrectomized eyes that had undergone silicone oil (SiO) tamponade. The G-PPV group consists of previously vitrectomized eyes with 23G pars plana vitrectomy (PPV) surgery performed more than 3 months before enrollment, did not have SiO tamponade, or had undergone prior SiO tamponade. The G-NVIT group includes eyes with intact vitreous bodies. Being treatment-naïve to intravitreal injections is not a prerequisite for participating in the trial, whereas all participants' eyes are to be treatment-naïve to antiglaucoma medications (not even temporary IOP lowering treatment was administered following SiO implantation or PPV surgery) and should have no signs of glaucomatous optic nerve disease. Patients were of Caucasian ancestry and ≥18 years of age.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

51

Study design details

Setting

Patients requiring intravitreal aflibercept are enrolled in one of the three study arms at the Department of Ophthalmology, University of Szeged, Hungary, between March 2022 and February 2025. The G-SiO group included previously vitrectomized eyes that had undergone silicone oil (SiO) tamponade. The G-PPV group consisted of previously vitrectomized eyes with 23G pars plana vitrectomy (PPV) surgery performed more than 3 months before enrollment, did not have SiO tamponade, or had undergone prior SiO tamponade. The G-NVIT group included eyes with intact vitreous bodies.

Interventions

Intraocular pressuse (IOP) was evaluated before and immediately after intravitreal aflibercept injection and at 5, 15, 30, 60, and 180 min, day 1, and week 1 postinjection. IOP measurements were taken with iCare-100 rebound tonometry (RBT) and Goldmann applanation tonometry (GAT) in the seated position sequentially.

Comparators

No comparator drug was used

Data analysis plan

Sample size estimation was based on a two-way repeated-measures ANOVA (between-groups within-time interaction), assuming a standardized effect size of f = 0.25 (medium), 3 independent groups, 9 repeated measurements, power = 95%, α = 0.05, correlation among measures = 0.40, and a Greenhouse–Geisser ε = 0.50. The minimum required sample size was 51 patients, computed in G*Power 3.1.9.7.

Continuous data were expressed as mean ± standard deviation (SD) or median (first quartile [Q1] and third quartile [Q3]) for symmetrical or skewed distributions, respectively. Categorical data were expressed as the number of cases (frequencies) or percentages (relative frequencies).

The relationships between the categorical variables were investigated by the Chi-squared test for independence.
Continuous variables in the three cohorts were compared with the one-way analysis of variance (ANOVA), Welch ANOVA, or Kruskal–Wallis test for symmetrical or skewed distributions, respectively. Post hoc comparisons for Welch ANOVA were conducted by Games–Howell tests.
IOP was analyzed with a linear mixed-effects model including fixed effects for group (vitreous status), time, and their interaction. Patient clustering was modeled with a random intercept, and within-eye repeated measurements. Estimated marginal means for group (vitreous status) at different timepoints were obtained and Bonferroni-adjusted between-group comparisons at each time point were performed. This specification accommodates unequal variances over time, serial correlation within eyes, and patient-level clustering.
IOP levels at all timepoints with respect to all examined parameters such as age, sex, AL, ACD, CCT, lens, and angle status were analyzed also with a linear mixed-effects model.
The agreement between GAT and RBT was analyzed with the Bland–Altman method
Calculations were conducted using IBM SPSS Statistics version 29.0.0.0 (241). P-values <0.05 were regarded as significant.

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 source(s), other

Department of Ophthalmology, University of Szeged

Data sources (types)

Clinical trial

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