CATALYST: Cataract Surgery in Conjunction with Ab-interno Canaloplasty Compared to Cataract Surgery Only in Patients with Mild to Moderate Primary Open-Angle Glaucoma

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To demonstrate the clinical efficacy and safety profile of canaloplasty utilizing the iTrackTM Advance canaloplasty device performed via an ab-interno surgical technique achieves:1. Enhanced IOP reduction at 12 months due to the techniques ability...

Ethical review	Approved WMO
Status	Pending
Health condition type	Glaucoma and ocular hypertension
Study type	Interventional

Summary

ID

NL-OMON57334

Source
ToetsingOnline

Brief title
CATALYST study

Condition

- Glaucoma and ocular hypertension

Synonym
Cataract and glaucoma; clouding of natural lens and damage to optic nerve

Research involving
Human

Sponsors and support

Primary sponsor: NOVAEYE Medical
Source(s) of monetary or material Support: Financiering via NOVA EYE medical

Intervention

Keyword: Canaloplasty, Cataract, Glaucoma, Intraocular pressure

Outcome measures

Primary outcome

Primary Effectiveness endpoints:

1. The mean reduction in IOP at 12-months compared to baseline in the test

group is statistically significantly greater than that of the control group

2. The mean reduction in number of glaucoma medications at 12-months compared

to baseline in the test group is statistically significantly greater than that

of the control group

Secondary outcome

Secondary Effectiveness endpoints:

The primary efficacy endpoints will be analysed as secondary endpoints at

24-months as part of the followup analysis at 24-months.

1. % of patients with complete success of the procedure at 12-month, defined

as: Complete success = Postoperative IOP at 12-month <= 18mmHg and the number of

medications is zero, and without any secondary interventions.

2. % of patients with qualified success of the procedure, defined as: Qualified

success = Postoperative IOP at 12-month <= 18mmHg and the number of medications

is > 0, and without any secondary interventions

3. % of patients with complete success of the procedure at 12-month, defined

as: Complete success = Postoperative IOP at 12-month <= 15mmHg and the number of medications is zero, and without any secondary interventions

4. % of patients with qualified success of the procedure, defined as: Qualified success = Postoperative IOP at 12-month <= 15mmHg and the number of medications is > 0, and without any secondary interventions

5. % of patients with greater than 20% reduction in IOP at 12-month follow-up

6. % of patients with IOP less than/equal to 15 mmHg at 12-month follow-up

7. % reduction in mean number of medications as compared to Screening vs 12-month follow-up

8. % of patients medication-free at 12-month follow-up

9. % of patients on one or less medications at 12-month follow-up

10. Quality of life Questionnaire evaluation

All effectiveness endpoints will also be analyzed at the 24- months* time point.

Safety Endpoints:

1. Summary of Complications/Adverse Events at 12-months

2. Best corrected visual acuity (BCVA) at 12-months

3. Endothelial cell count (ECC) at 12-months compared to baseline

4. Visual field progression: change in visual field mean deviation score (dB) at 12 months compared to baseline

All safety endpoints will also be analyzed at the 24-months time point.

Study description

Background summary

Hitherto, the safety and effectiness of the iTrackTM Advance Canaloplasty device, performed via an ab-interno approach, combined with cataract surgery has not been established as compared to cataract surgery on its own. Nevertheless, this procedure could potentially reduce intraocular pressure to a larger extent, thereby also reducing glaucoma medication use.

Study objective

To demonstrate the clinical efficacy and safety profile of canaloplasty utilizing the iTrackTM Advance canaloplasty device performed via an ab-interno surgical technique achieves:
1. Enhanced IOP reduction at 12 months due to the techniques ability to address all aspects of the outflow system;
2. Reduced medication use at 12 months due to the techniques ability to address all aspects of the outflow system
3. Minimal surgical and post-operative complications;
4. Reduced endothelial cell loss which is attributed to the tissue-sparing, atraumatic mechanism

Study design

This is a prospective, multicenter, randomized, single-masked, post-market clinical trial with follow-up through 12 months

Intervention

Intervention: iTrackTM Advance canaloplasty device (Nova Eye, Inc.) combined with cataract surgery

Control: cataract surgery

Study burden and risks

Both the cataract surgery and the canaloplasty procedure are performed as per normal clinical routine. Therefore, the risks associated with the surgical procedures are unchanged in the study compared to routine clinical care No additional invasive assessments are performed throughout the study that would increase the risk to the patients.
The follow-up includes one additional visit compared to routine clinical care, as well as Quality of Life Questionnaire

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a) Male or female subjects, 55 years or older at the time of surgery.
b) Diagnosed with mild to moderate primary open angle glaucoma, i.e., mean deviation
score must be better than or equal to -12.0 dB, as documented in patient's medical
record substantiated using fundoscopic exam or OCT, and at least one visual field
test with the Humphrey automated perimeter using the SITA Standard 24-2 testing algorithm.
c) The visual field test may be historical (within 3 months prior to Screening Visit). If
needed, visual field testing may be repeated between the Screening Visit and

the
Surgery Visit.
d) At the Screening Visit, IOP of <= 25 mmHg while on 1-4 ocular hypotensive medications.
e) Shaffer grade of >= III in all four quadrants.
f) Endothelial cell density >2000 (cells/mm2) (average of 3 measurements).
g) Patients with visually significant cataract.
h) Able and willing to comply with the study procedures and attend all follow-up visits.
i) Understands and signs the informed consent.

Exclusion criteria

a) Any of the following prior treatments for glaucoma (study eye):
1. Laser Trabeculoplasty
i) Selective Laser Trabeculoplasty (SLT) conducted within 6-months of
the Screening Visit
ii) Prior Argon Laser Trabeculoplasty
2. Endocyclophotocoagulation (ECP) or Micropulse laser
3. iStent or iStent Inject
4. Hydrus Microstent
5. Trabeculectomy or other bleb forming procedure including Xen, Express, and glaucoma
drainage device/valve.
6. Prior canaloplasty (ab-interno and ab-externo)
7. Prior goniotomy, or trabeculotomy (ab-externo and ab-interno)
8. Suprachoroidal stent (e.g., Cypass, iStent Supra, XEN)
9. Concurrent IOP-lowering procedure other than use of the iTrackTM Advance canaloplasty
device at the time of surgery (e.g., ECP, CPC, etc.)
10. Previous treatment with iTrackTM (Note: permitted if fellow eye only was treated)
b) Acute angle closure, traumatic, congenital, malignant, uveitic or neovascular
glaucoma.
c) Eyes with complications related to cataract extraction or IOL implantation will be
removed from the study.
d) Use of systemic medications (either current, within 30 calendar days of Screening
exam, or anticipated) that may cause an increase in IOP, (e.g., systemic steroids including
inhaled and oral steroids used on a regular basis)
e) Ocular diseases (such as corneal endothelial dystrophy, intraocular

inflammation and
infection) that could affect the corneal endothelium; and systemic diseases (such as
congenital abnormalities) that could affect the corneal endothelium.
f) No other clinically significant concurrent intraocular pathology other than glaucoma and
cataract at the time of surgery.
g) History of penetrating keratoplasty or another corneal transplant
h) BCVA of 20/200 or worse in the fellow eye not due to cataract.
i) Participation (<= 30 days prior to Screening) in an interventional trial which could have a
potential effect on the study outcome, as determined by the study Investigator
j) Women of childbearing potential if they are currently pregnant or intend to become
pregnant during the study period; are breast-feeding; or are not in agreement to use
adequate birth control methods to prevent pregnancy throughout the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	iTrackTM Advance canaloplasty device

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-03-2025
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05786196
CCMO	NL86827.068.24