

# 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 iTrack™ Advance canaloplasty device performed via an ab-interno surgical technique achieves:1. Enhanced IOP reduction at 12 months due to the techniques ability...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Glaucoma and ocular hypertension
<b>Study type</b>	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  $\leq$  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  $\leq$  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  $\leq$  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  $\leq$  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 effectiveness of the iTrack™ 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 iTrack™ 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: iTrack™ 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

### Public

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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  $\leq 25$  mmHg while on 1-4 ocular hypotensive medications.

e) Shaffer grade of  $\geq$  III in all four quadrants.

f) Endothelial cell density  $>2000$  (cells/mm<sup>2</sup>) (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 iTrack<sup>TM</sup> Advance canaloplasty

device at the time of surgery (e.g., ECP, CPC, etc.)

10. Previous treatment with iTrack<sup>TM</sup> (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 ( $\leq 30$  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:	iTrack™ Advance canaloplasty device
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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