THE SAFETY AND EFFECTIVENESS OF THE HYDRUS AQUEOUS IMPLANT FOR LOWERING INTRAOCULAR PRESSURE IN GLAUCOMA PATIENTS UNDERGOING CATARACT SURGERY, A PROSPECTIVE,MULTICENTER, RANDOMIZED, CONTROLLED CLINICAL TRIAL

Published: 03-07-2014
Last updated: 20-04-2024

The objective of this study is to demonstrate the safety and effectiveness of the Hydrus Aqueous Implant for lowering IOP in patients with primary open-angle glaucoma (POAG) who are undergoing concurrent cataract surgery.

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

Summary

ID

NL-OMON40947

Source
ToetsingOnline

Brief title
Hydrus 4 study

Condition

- Glaucoma and ocular hypertension

Synonym
Intraocular pressure

Research involving
Human

Sponsors and support

Primary sponsor: Ivantis, Inc.
Source(s) of monetary or material Support: Ivantis;Inc.

Intervention

Keyword: Effectiveness, Hydrus, Intraocular, Safety

Outcome measures

Primary outcome

Primary outcome parameters will include:

Effectiveness

The primary effectiveness endpoint for this study is:

• Reduction of at least 20% (i.e., >= 20%) in mean diurnal IOP from baseline at

24 months following medication washout.

Safety

• Safety outcomes include loss of lines of BCVA, slit lamp and fundus

examination findings, ECD change, and the incidence of complications and

adverse events.

Secondary outcome

The secondary effectiveness endpoint for this study is:

• The mean diurnal IOP change from baseline at 24 months will be compared

between the Hydrus and control groups.

Study description

Background summary

Since glaucoma is the second leading cause of irreversible blindness in the general population in the world, it is important to treat this condition.

Study objective

The objective of this study is to demonstrate the safety and effectiveness of the Hydrus Aqueous Implant for lowering IOP in patients with primary open-angle glaucoma (POAG) who are undergoing concurrent cataract surgery.

Study design

This clinical trial is a prospective, randomized, controlled, multicenter, study. Qualified subjects will undergo cataract surgery, placement of a standard monofocal intraocular lens (IOL), and will then be randomized to receive the Hydrus Aqueous Implant (test group) or no treatment (control group).

Patients with refractory glaucoma (i.e., who have failed maximum medical treatment or filtration/cilioablative surgery) or secondary glaucoma are excluded from this study.

After informed consent is obtained, subjects will be evaluated for eligibility based on glaucoma severity, ocular health, and visual acuity. Following successful screening, use of all glaucoma medications (topical and oral) will be discontinued for a period of "washout" to establish a qualifying medication-free IOP value. Intraoperatively, after successful completion of the cataract procedure, patients will be randomized into treatment or control arms. Clinical follow up will be scheduled per the study visit schedule over the course of the 24 month study, and examinations will be repeated to monitor ocular health. At the 1 and 2 year follow up, those patients on ocular hypotensive medications will be instructed to washout, and then have the washed out diurnal IOP evaluation. Annual follow up will occur up to 5 years in support of a future PMA application.

In the initial phase of study, 75 subjects (50 treated and 25 controls) will be randomized and followed for 3 months. The 3-month follow-up data will be submitted to the FDA to request approval for expansion to include the full study population of an additional

483 randomized subjects.

Intervention

Implantation Hydrus Aqueous Implant

Study burden and risks

The risks associated with the use of the Hydrus implant are likely to be mild and rare. Because of the nature of the procedure, the risk profile should be approximately the same as cataract surgery alone. This is consistent with the available data from pilot studies of the device. Information learned from this study may help by adding to medical knowledge in this area and better treatment for people in the future. The potential benefit to participating in this study is that there may be drainage of excess fluid from the eye, a reduction in pressure of the eye (stabilization of glaucoma status), and reduction or elimination of the need for glaucoma medications in the treated eye.

Contacts

Public
Ivantis, Inc.

38 Discovery, Suite 150 -
Irvine, CA 92618
US
Scientific
Ivantis, Inc.

38 Discovery, Suite 150 -
Irvine, CA 92618
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

INCLUSION CRITERIA:
Subjects must meet the following inclusion criteria to be eligible for the study eye
* Male and female patients, at least 45 years of age
* An operable age-related cataract with BCVA of 20/40 or worse, eligible for phacoemulsification; if BCVA is better than 20/40, testing with a BAT meter on a medium setting must result in BCVA 20/40 or worse
* A diagnosis of POAG treated with 1 to 4 hypotensive medications
* Optic nerve appearance characteristic of glaucoma
* Medicated IOP <= 31 mmHg
* Diurnal IOP >= 22 mmHg and <= 34 mmHg after wash out of ocular hypotensive medications
* IOP increase >= 3 mmHg after wash out of ocular hypotensive medications
* Visual field examination using Humphrey 24-2 SITA standard, meeting protocol specified minimum criteria for glaucoma defined as:
- Mild: visual field loss on Humphrey visual field testing, with mean deviation (MD) between 0 and -6dB; fewer than 25% of points depressed below the 5% level and fewer than 15% of points depressed below the 1% level on pattern deviation plot; and no point within central 5° with sensitivity <15dB
- Moderate: visual field loss on Humphrey visual field testing, with mean deviation worse than -6dB but no worse than -12dB; fewer than 50% of points depressed below the 5% level, and fewer than 25% of points depressed below the 1% level on pattern deviation plot; no points within central 5° with sensitivity of <=0dB; and only one hemifield containing a point with sensitivity <15dB within
5° of fixation
* In subjects where the VF exam is not confirmatory for glaucomatous defect, retinal nerve fiber layer optical scanning laser imaging supporting ophthalmoscopy findings shall be performed
* Shaffer grade >= III in all four quadrants
* Cup:disc (c:d) ratio <= 0.8
* Absence of peripheral anterior synechiae (PAS), rubeosis or other angle abnormalities that could impair placement of the implant
* Subject is able and willing to attend scheduled follow-up exams for 2 years postoperatively (and up to 5 years postoperatively as part of a post-approval study)
* Subject understands and signs the informed consent;INTRAOPERATIVE ELIGIBILITY CRITERIA
Individuals who meet the following intraoperative eligibility criteria in the study eye will be randomized into the treatment or control arms of this study.;Subjects must have:
* An intact and centered capsulorrhexis

* An intact posterior capsular bag
* A well-centered monofocal IOL placed in the capsular bag
* A clear view of an open angle and visualization of the angle with direct gonioscopy following intracameral instillation of a miotic agent, and;Subjects must not have:
* Evidence of zonular dehiscence/rupture
* Intraoperative floppy iris syndrome

Exclusion criteria

EXCLUSION CRITERIA
Excluded from the study will be individuals with the following characteristics. Unless specified otherwise, all ocular criteria refer to the study eye only.
* Closed angle forms of glaucoma
* Congenital or developmental glaucoma
* Secondary glaucoma (such as neovascular, uveitic, pseudoexfoliative, pigmentary, lensinduced,
steroid-induced, trauma induced, or glaucoma associated with increased episcleral venous pressure)
* Use of more than 4 ocular hypotensive medications (combination medications count as two medications)
* Previous argon laser trabeculoplasty, trabeculectomy, tube shunts, or any other prior filtration or cilioablative surgery
* Prior surgery for an ab-interno or ab-externo device implanted in or through the Schlemm*s Canal
* Inability to complete a reliable 24-2 SITA Standard Humphrey visual field on the study eye at screening (fixation losses, false positive errors and false negative errors should not be greater than 33%)
* Use of oral hypotensive medication for glaucoma for treatment of the fellow eye
* Subjects with advanced glaucoma or any subject who presents with an unacceptable risk to the subject of a washout of ocular hypotensive medications
* Best corrected visual acuity worse than 20/80 in the fellow eye
* A 24-2 SITA Standard Humphrey visual field mean deviation (MD) of worse than -12dB in the fellow eye
* Central corneal thickness > 620 microns and < 480 microns
* Proliferative diabetic retinopathy
* Previous surgery for retinal detachment
* Previous corneal surgery or clinically significant corneal dystrophy, e.g., Fuch*s dystrophy (>12 confluent guttae)
* Unclear ocular media preventing visualization of the fundus or anterior chamber angle
* Degenerative visual disorders such as wet age-related macular degeneration
* Clinically significant ocular pathology, other than cataract and glaucoma
* Clinically significant ocular inflammation or infection within 6 months prior to screening
* Presence of extensive iris processes that obscure visualization of the trabecular meshwork
* Unable to discontinue use of blood thinners in accordance with surgeon*s standard postoperative instructions

* Known or suspected elevated episcleral venous pressure due to Sturge Weber, nanophthalmos, orbital congestive disease
* Uncontrolled systemic disease that in the opinion of the Investigator would put the subject*s health at risk and/or prevent the subject from completing all study visits
* Current participation or participation in another investigational drug or device clinical trial (which includes the fellow eye) within the past 30 calendar days
* Pregnant or nursing women; or women of child bearing age not using medically acceptable contraceptives

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	HYDRUS AQUEOUS IMPLANT
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-07-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO Date:	03-10-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NCT01539239
CCMO	NL48178.075.14