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

Published: 30-03-2011
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The purpose of this study is to expand knowledge of the IVANTIS Hydrus Implant's ability to decrease intraocular pressure (the pressure in the eye).

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

Summary

ID

NL-OMON39988

Source
ToetsingOnline

Brief title
CP-10-001 (Ivantis, Hydrus, Implant)

Condition

- Glaucoma and ocular hypertension

Synonym
lowering intraocular pressure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cataract Surgery, Glaucoma Patients, Hydrus II Trial, Intraocular Pressure

Outcome measures

Primary outcome

The primary effectiveness endpoint for this study is IOP at 12 months following

the terminal wash-out of all glaucoma medications.

Secondary outcome

Secondary effectiveness endpoints include:

• The proportion of eyes with reduction in IOP of at least 20% following

wash-out, as compared to the washed-out baseline in each study group.

• Change in best corrected visual acuity (BCVA) as measured by EDTRS, in the

study eye from baseline to 12 months.

• The proportion of eyes with IOP > 5 mmHg to £ 19 mmHg at 12 months post

washout.

• Diurnal IOP at 24 months following the wash-out of all glaucoma medications.

• Diurnal IOP at 36 months following the wash-out of all glaucoma medications.

Study description

Background summary

Glaucoma is a leading cause of irreversible blindness, and is associated with increased intraocular pressure (IOP). Ivantis has developed the HydrusTM Aqueous Implant as a surgical alternative to hypotensive glaucoma medications. The Hydrus Implant is designed to enhance the function of the natural aqueous outflow pathway of the eye in order to reduce IOP.

Study objective

The purpose of this study is to expand knowledge of the IVANTIS Hydrus Implant's ability to decrease intraocular pressure (the pressure in the eye).

Study design

HYDRUS II is a post-market, prospective, single masked, randomized, controlled, multicenter clinical trial comparing CE surgery + Hydrus Implant to CE surgery alone for the reduction of IOP in patients with a positive diagnosis for POAG or psuedoexfoliative glaucoma.

Potential study participants will be screened for eligibility, and if qualified after initial screening, use of all glaucoma medications (topical and oral) will be discontinued for a period of "wash-out"; the duration of wash-out will be determined by the specific medication(s) used. Following wash-out, the patient will return for a baseline evaluation, and if found to be eligible, will be scheduled for cataract surgery.

One hundred (100) qualified subjects will be randomized to treatment or control arms at the time of the procedure. Post operative follow up will be conducted at regular intervals.

The primary effectiveness analysis will be performed at 12 months, after a "wash-out" of all glaucoma medications. Secondary effectiviness analysis will be performed at 24 and 36 months following wash-out of all glaucoma medications.

Roll-ins (non-randomized): Up to 5 roll-in subjects may be enrolled at each site/per surgical operator; these subjects will be included in the study safety cohort but will not be included in the evaluation of effectiveness. The requirement for roll-in subjects may be waived if the investigator has previous experience with the HydrusTM Aqueous Implant.

Intervention

Not applicable.

Study burden and risks

The risks associated with the use of the Hydrus implant are likely to be mild and infrequent. 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. The potential benefits of a surgical alternative to medical therapy for elevated IOP are substantial, and should be investigated.

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

• Male and female patients, from 21 to 80 years of age.
• A diagnosis of primary open angle glaucoma (POAG) or pseudoexfoliative glaucoma.
• At the Screening Visit, a mean (or median) IOP of <24 mmHg on 4 or fewer glaucoma medications.
• At the Baseline Visit, a mean unmedicated diurnal IOP of >= 21 mmHg and <= 36 mmHg. Alternately, an average of the unmedicated Baseline (non-diurnal) IOP and the Operative Day IOP >= 21 mmHg and <= 36 mmHg.
• An operable age-related cataract with visual impairment or glare, eligible for phacoemulsification.
• Diagnosis of glaucoma substantiated by ophthalmoscopy and an automated visual field test using a Humphrey automated visual field analyzer within 90 days prior to the Screening Visit. Mean deviation score must be <0.
• If visual field testing is not confirmatory, but the subject has utilized ocular hypotensive medications for >= 3 months prior to enrollment, optical scanning lasers and optic disc photography confirming disc morphology may be used to establish the diagnosis of glaucoma. Acceptable optical scanning laser diagnostics include:
1. Heidelberg Retina Tomography (HRT) abnormal nerve fiber layer (NFL) findings indicated by a yellow exclamation mark and/or a red x.
2. Zeiss/Humphrey Glaucoma Diagnostic unit - GDx abnormal NFL findings with a Nerve Fiber Index (NFI) reading of > 31 and/or < 5% p-value indicator for NFL.
3. Optical Coherence Testing (OCT) abnormal NFL findings in the red or yellow areas, below the area of normal on the Analysis of Thickness.
• Gonioscopy confirming normal angle anatomy at site of implantation.
• Anterior chamber angle Shaffer grade of >= III.
• Able to understand the requirements of the study and willing to follow study instructions, provide written informed consent, and agree to comply with all study requirements, including the required study follow-up visits.

Exclusion criteria

• Closed angle forms of glaucoma.
• Secondary glaucoma (such as neovascular, uveitic, traumatic, steroid induced, lens induced); glaucoma associated with increase episcleral venuous pressure; congenital or developmental glaucoma.
• Significant risk due to washout of medication.
• Previous argon laser trabeculoplasty (ALT), cyclodestructive procedure, trabeculectomy, tube shunts, or any incisional glaucoma surgical procedure.
• 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 shoud not be greater than 33%).
• Use of more than 4 ocular hypotensive medications. (Note: Combination medications count as 2 medications.)

• Central corneal thickness > 620 or < 480 microns.
• Best corrected visual acuity worse than 20/80 in the fellow eye.
• Proliferative diabetic retinopathy.
• Previous surgery for retinal detachment.
• Clinically significant corneal dystrophy.
• Previous corneal surgery.
• Previous refractive surgery, including previous phakic IOL surgery.
• Previous or planned iridectomy surgery on the study eye.
• Degenerative visual disorders such as wet age-related macular degeneration or non-retinal laser surgery.
• Clinically significant ocular pathology, other than cataract and glaucoma.
• Clinically significant ocular inflammation or infection within thirty days prior to screening.
• 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.
• Concurrent participation in another clinical study , or completion in another study within the past 30 days.
• Pregnant, nursing females, or women who are of childbearing potential who are not using an acceptable method of contraception.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2011
Enrollment:	17
Type:	Actual

Medical products/devices used

Generic name:	Hydrus Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-03-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-08-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL35079.078.10