PACT GLAUCOMA TREATMENT OF THE CORNEA SCLERAL TISSUE.

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The purpose of this clinical trial is to evaluate the clinical performance of the PACT procedure in lowering intra-ocular pressure in subjects with elevated intra-ocular pressure, as a function of glaucoma or ocular hypertension.

Ethical review	Not approved
Status	Will not start
Health condition type	Glaucoma and ocular hypertension
Study type	Interventional

Summary

ID

NL-OMON33442

Source
ToetsingOnline

Brief title
PACT study

Condition

- Glaucoma and ocular hypertension

Synonym
Glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Medpole SA
Source(s) of monetary or material Support: door het bedrijf: PriaVision Inc.

Intervention

Keyword: cornea, Glaucoma, PACT procedure

Outcome measures

Primary outcome

The primary outcome measure will be a reduction of IOP.

Secondary outcome

Other key evaluation criteria include uncorrected and best corrected distance visual acuity, uncorrected and best-distance corrected near visual acuity, accommodative amplitude, manifest refraction, complication rates, and adverse event rates..

Study description

Background summary

Glaucoma is a disease of the optic nerve. The optic nerve is a nerve which can be found in your eye and which is responsible for carrying images from the eye to the brain. The term ocular hypertension refers to any situation in which the fluid pressure inside the eye, called intra-ocular pressure, is higher than normal.
The purpose of this clinical trial is to evaluate the clinical performance of the PACT procedure in lowering intra-ocular pressure in subjects with elevated intra-ocular pressure, as a function of glaucoma or ocular hypertension.
This trial will demonstrate that the PACT corneo-scleral treatments are effective at reducing intra-ocular pressure in eyes with elevated intra-ocular pressure.

Study objective

The purpose of this clinical trial is to evaluate the clinical performance of the PACT procedure in lowering intra-ocular pressure in subjects with elevated intra-ocular pressure, as a function of glaucoma or ocular hypertension.

Study design

Design: Prospective, multi-center, open-label, non-randomized clinical trial.

Number of Sites: Up to three European clinical sites will participate.

Duration: One year.

Intervention

VISITS AND PROCEDURES:
The pre-operative visit will include an assessment of subject qualifications for inclusion in the study according to the protocol inclusion/exclusion criteria. Informed consent must be signed by those patients who agree to participate. Key pre-operative data collection will include medical history, intra-ocular pressure, visual acuity (near and distance), refraction, keratometry, computerized videokeratography and slit lamp findings. The surgical visit will include procedures standard to outpatient ophthalmic laser surgery. Key data will be recorded from the surgical procedure including laser treatment parameters, medications, complications, and adverse events. Post-operative key data collection includes visual acuity, refraction, applanation tonometry, keratometry, computerized videokeratography slit lamp findings, complications and adverse events.

Study burden and risks

RISK/BENEFICE FOR PATIENT:
Potential adverse events of the Sunrise Hyperion LTK laser system include: corneal infilitrates or ulcer; uncontrolled intraocular pressure (IOP); late onset of corneal haze > 6 months, with loss of greater than or equal to 2 lines of best spectacle corrected visual acuity (BSCVA); decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later; retinal vascular accidents; retinal detachment.
Potential Benefits for subjects include but are not limited to: a decrease in intraocular pressure, reduce or eliminate the need for glaucoma medications, and improvement in uncorrected vision at near.

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

Subject Inclusion Criteria;One eye of the subject may be enrolled and treated in this clinical study.;Enrollment in this study is limited to subjects who meet the following inclusion criteria in the operative eye(s):;1) Male or female, of any race, and at least 43 years old at the time of the pre-operative examination and signing the consent form.
2) BSCVA of 20/25or better.
3) Have emmetropia (defined as a spherical equivalent of +/- 0.50 diopters with no more than 1.00 diopters of astigmatism.
4) Intra-ocular pressure greater than 24 mm of Hg adjusted for central corneal thickness.
5) Willing and medically safe to have a wash out of current ocular medications for two weeks (four weeks for topical prostaglandins).
6) Willing and capable of returning for follow-up examinations for the duration of the study (12 months).
7) MRSE between 3 month visits changes less than 0.50 D

Exclusion criteria

Subject Exclusion Criteria;Subjects are not eligible for enrollment if they meet any of the following exclusion criteria:;1) Women who are pregnant, breast-feeding, or intend to become pregnant over the course of the study, as determined by verbal inquiry.
2) No more than two glaucoma pressure lowering ophthalmic drugs.

3) Concurrent use of topical or systemic medications that may impair healing.
4) History of any of the following medical conditions, or any other condition that could affect wound healing: collagen vascular disease, autoimmune disease, immunodeficiency diseases, ocular herpes zoster or simplex, endocrine disorders (including, but not limited to unstable thyroid disorders and diabetes), lupus, and rheumatoid arthritis.
5) History of prior intraocular or corneal surgery (including cataract extraction), active ophthalmic disease (other than glaucoma) or, retinal detachment/repair, clinically significant lens opacity or clinical evidence of ocular trauma
6) Evidence of keratoconus, corneal dystrophy or irregularity, or abnormal videokeratography.
7) Known sensitivity or inappropriate responsiveness to any of the medications used in the post-operative course.
8) Participation in any other clinical study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Not approved

Date:	08-06-2010
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL27509.015.09