Selective Laser Trabeculoplasty for Primary Angle-Closure Glaucoma: a pilot case study

Submission date	Recruitment status	Prospectively registered
05/05/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
03/07/2006	Completed	Results
Last Edited	Condition category	Individual participant data
11/08/2008	Eye Diseases	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Michael Belkin

Contact details

Goldschleger Eye Research Institute Tel Aviv University Sheba Medical Center Tel Hashomer Israel 52621

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Acronym

SLT for PACG Study

Study objectives

To determine whether selective laser trabeculoplasty (SLT) using a Q-switched frequency doubled neodymium-doped yttrium aluminium garnet (Nd:YAG) laser is effective in lowering intraocular pressure in patients with primary angle-closure glaucoma (PACG).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

- 1. Singapore Eye Research Institute (SERI-Singapore) (Ref: R424/19/2005) dated 27/10/2005
- 2. United Christian Hospital (Hong Kong) (Ref: KC/KE05-0073/FR-3) dated on 15/06/2005

Other ethics approval from Chulalongkorn University and Hospital (Thailand), St. Luke's Medical Centre (Philippines) and National University Hospital (Singapore).

Study design

Prospective, observational, uncontrolled, non-comparative study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Primary angle-closure glaucoma

Interventions

Selective laser trabeculoplasty (SLT)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Intraocular pressure (IOP) at regular intervals of follow-up with the final IOP being measured at six months after the last treatment. Successful outcome defined as greater or equal to 20% reduction in IOP from pre-laser levels.

Secondary outcome measures

IOP measured on other eye if both eyes are eligible for the study.

Overall study start date

01/07/2005

Completion date

01/07/2006

Eligibility

Key inclusion criteria

- 1. PACG
- 2. Intraocular pressure 21 28 mmHg on one or more topical medicine in presence of patent iridotomy
- 3. At least two months since last iridotomy
- 4. Aged over 21 years old

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

150

Key exclusion criteria

- 1. Secondary causes of angle-closure
- 2. Corneal abnormalities
- 3. Advanced glaucomatous optic neuropathy
- 4. Patient blind in one eye

Date of first enrolment

01/07/2005

Date of final enrolment

01/07/2006

Locations

Countries of recruitment



Thailand

Study participating centre Goldschleger Eye Research Institute Tel Hashomer Israel 52621

Sponsor information

Organisation

Ellex Medical Pty. Ltd. (Australia)

Sponsor details

82 Gilbert Street Adelaide, SA Australia 5000

Sponsor type

Industry

Website

http://www.ellex.com

Funder(s)

Funder type

Industry

Funder Name

Ellex Medical Pty Ltd (Australia)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration