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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Hong Kong

Israel

Philippines

Singapore

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 plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration