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Is repeated laser treatment effective in intraocular pressure (IOP) reduction?

Submission date 28/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/03/2010	**Overall study status** Completed	
Last Edited 04/10/2011	**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
Intraocular pressure reduction after repeated selective laser trabeculoplasty (SLT): A prospective randomised clinical trial

Study objectives
Is repeated laser treatment as effective as non-repeated treatment in decreasing IOP?

Glaucoma is a progressive neuropathy localised in the optic nerve that may lead to blindness. Reducing IOP seems to be the only treatment to stop progression in glaucoma. There are several methods to reduce IOP: medical treatment, laser and surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee of the Karolinska Institutet approved on the 28th of January 2009 (ref: 2009/ 1:1)

Study design
Single centre prospective randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet (in Swedish)

Health condition(s) or problem(s) studied
Glaucoma

Interventions
Patients will be treated with SLT 2 and randomly divided to treatment in adjacent place (classically treated) or in the same place. Then will be checked at 1 month, 3 months, 6 months and 12 months after SLT 2.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
IOP after repeated SLT in the same area against repeated SLT treatment in adjacent areas.
IOP will be measured with the Goldmann applanation tonometry (GAT) at base line (before treatment) and then 1, 3, 6 and 12 months after treatment.

Secondary outcome measures
1. Genders influence on IOP
2. Ages influence on IOP
3. Pseudoexfoliations influence on IOP
4. Inflammation measurements using a slit-lamp and according to the international classification of the Standardization of Uveitis Nomenclature (SUN) Working Group

Overall study start date
01/02/2010

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Patients suffering from glaucoma or Ocular Hypertenstion (OHT)
1.1. Primary open angle glaucoma (POAG) - open angle defined as > grade II (Shaffer classification: scale 0-IV) assessed by gonioscopy
1.2. Pigmentary and pseudoexfoliative glaucoma
1.3. OHT to be treated with SLT 2 both with and without eye-drops.
2. If both eyes must be treated just one will be selected at random.
3. Older than 18 years, no upper age limit
4. Men and women

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria

1. Patients treated with cortisone or immunosuppressive drugs
2. Patients suffering from ocular or systemic inflammatory diseases
3. Patients with Possner-Schlossman syndrome
4. Patients that cannot be treated with SLT due to eyes characteristics (shallow anterior chamber) or bad collaboration

Date of first enrolment
01/02/2010

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Sweden

Study participating centre
Glaucoma Department
Stockholm
Sweden
112 82

Sponsor information

Organisation
St Eriks Eye Hospital (Sweden)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03z5b5h37

Funder(s)

Funder type
Charity

Funder Name
Karolinska Institute Research Foundation (Sweden)

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