

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

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| Submission date 28/01/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 16/03/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 04/10/2011 | Condition category Eye Diseases | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

01/12/2010

Eligibility

Key inclusion criteria

1. Patients suffering from glaucoma or Ocular Hypertension (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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR
<https://ror.org/03z5b5h37>

Funder(s)

Funder type
Charity

Funder Name
Karolinska Institute Research Foundation (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration