

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

To compare effect of selective laser trabeculoplasty on IOP in Primary open angle and pseudoexfoliative glaucoma

Protocol summary

Summary

Glaucoma is one of the most important cause of blindness in the world .The most common cause of glaucoma is open angle glaucoma. Because medical treatment of glaucoma has a high rate of non-compliance due to chronicity of disease, laser treatment of open angle glaucoma is an option as a primary or adjuvant treatment. Selective laser trabeculoplasty introduced in 1997 and approved by FDA in 2001. In this laser by Q -Switch Frequency double ND: YAG pigmented TM cells stimulate in 3 nanosecond and IOP decrease without lateral disruption of TM .This laser is useful in primary open angle glaucoma, ocular hypertension, pigmentry, pseudoexfoliative and steroid induced glaucoma. Different studies have shown that mean IOP can decrease 4-6 mmHg in 6 month follow up. There are few studies in literature about comparison of 360 degree SLT in primary open angle and pseudoexfoliative glaucoma. In addition to decreasing IOP and number of anti-glaucoma medications this laser doesn't interfere with surgery and can increase patient compliance and we decide to evaluate effect of 360 degree SLT in a prospective study on IOP of patients with 1-POAG 2-pseudoexfoliative glaucoma with uncontrolled pressure who need at least 20% decrease of IOP or the same patients with newly diagnosis of POAG or PXF glaucoma who need at least 20% decrease of IOP in Rasoul Akram hospital.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008124558N1**

Registration date: **2010-10-10, 1389/07/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-10, 1389/07/18

Registrant information

Name

Arezou Miraftabi

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare effect of selective laser trabeculoplasty on IOP in Primary open angle and pseudoexfoliative glaucoma

Public title

To compare effect of selective laser trabeculoplasty on IOP in Primary open angle and pseudoexfoliative glaucoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with 1-POAG 2-pseudoexfoliative glaucoma with uncontrolled pressure who need at least 20% decrease of IOP or the same patients with newly diagnosed POAG or PXF glaucoma who need at least 20% decrease of IOP Exclusion criteria: previous ALT or intraocular surgery 2-Angle closure glaucoma in which TM is not visible 3-IOP>30 mmHg 4-Advanced visual field defect 6-central 10 degree involvement and split fixation 7-any intraocular disease

Age

To **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Eye research center, Rasoul Akram Hospital

Street address

Niayash street, Sattarkhan street, Rasoul Akram Hospital

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

478 م ت

Health conditions studied

1

Description of health condition studied

primary open angle and pseudoexfoliative glaucoma

ICD-10 code

H 40.1

ICD-10 code description

primary open angle glaucoma and PXF glaucoma

Primary outcomes

1

Description

Intraocular pressure

Timepoint

Control of IOP 2 hours, one day, one week, 3 months, 6 months after SLT and in the last follow up

Method of measurement

calibrated Goldman tonometer

Secondary outcomes

1

Description

complications of SLT

Timepoint

2 hours, one day, one week, 3 months, 6 months after SLT and in the last follow up

Method of measurement

complete SLit lamp exam and fundoscopy and gonioscopy

Intervention groups

1

Description

360 degree Selective laser trabeculoplasty with frequency double Neodymium YAG

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Dr.Arezoo Miraftabi

Street address

Niayesh street, SatarKhan Street, Rasoul Akram Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of
Medical Science

Full name of responsible person

Mrs Dehban

Street address

Hematt Highway ,Adjacent to Milad tower

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical
Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

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Dr Arezoo Miraftabi

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty