

Laser compared to topical medicine as primary treatment for glaucoma in Africa

Submission date 13/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/12/2015	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/12/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Glaucoma is an eye condition which develops when a fluid inside the eye (called the aqueous humour) cannot drain properly, causing pressure to build up that can result in damage to the optic nerve and nerve fibres from the retina. It often affects both eyes, generally with one being more affected than the other, and, over time, it can lead to a partial or complete loss of sight. Primary open angle glaucoma (POAG) is the chronic, slowly developing form of the condition. There is currently a debate regarding what is the best first-line (first choice) therapy for POAG for African patients. Most African practitioners advocate trabeculectomy surgery (where a small hole is created to allow the excess fluid to drain from the eye). However, they are much more likely to treat the condition with drugs because, amongst other reasons, their patients won't accept surgery. In the developed world, a range of first-line therapies including elective laser trabeculoplasty (SLT), have been advocated. SLT is a treatment where a laser beam is applied to the drainage channels of the eyes, which helps to unblock them and allow the aqueous humour to flow through them better, reducing the pressure. The purpose of this study is to compare a drug therapy (prostaglandin analogue) with SLT for the treatment of primary open angle glaucoma in an African population.

Who can participate?

African patients with established or newly diagnosed primary open angle glaucoma or patients with POAG currently on single drug therapy (excluding prostaglandin analogues) and elevated pressure in the eye (intraocular pressure).

What does the study involve?

Patients are randomly allocated into one of two groups. Those in group 1 are treated with SLT. Those in group 2 are provided with prostaglandin analogue with instructions for use and prescription to obtain supplies of the drug. Intraocular pressure is then measured at regular intervals for at least 12 months. Any side effects, complications or reoccurrence of high intraocular pressure are treated as appropriate for the duration of the study.

What are the possible benefits and risks of participating?

The benefits of taking part in the study include the encouragement and assistance to attend for follow-up for this chronic disease. In an African environment attendance for repeat review is

infrequent hence management will be improved for those taking part in the study. There are no additional risks from taking part in the study.

Where is the study run from?

1. Inkosi Albert Luthuli Central Hospital, Durban (South Africa)
2. Innovation Eye Centre, Kisii Eye Hospital (Kenya)

When is the study starting and how long is it expected to run for?

February 2014 to November 2018

Who is funding the study?

International Glaucoma Association (UK)

Who is the main contact?

Mr Ian Murdoch

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

To compare selective laser trabeculoplasty (SLT) with prostaglandin analogue as first line therapy in African Primary Open Angle Glaucoma (POAG) patients

Acronym

SLT vs medicine for POAG

Study objectives

Selective laser trabeculoplasty (SLT) may be an appropriate first line therapeutic option for primary open angle glaucoma (POAG) in an African setting

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University College London Ethical Committee, 01/10/2014, ref: 5497/001
2. Biomedical Research Ethics Committee (BREC), 15/05/2012, ref: BFC107/11
3. Aga Khan University Faculty of Health Sciences Research Ethics Committee, 06/05/2013, ref: 2012/24

Study design

Two centre randomised prospective 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 to request a participant information sheet

Health condition(s) or problem(s) studied

Primary open-angle glaucoma

Interventions

After informed consent all patients undergo a standardised examination to establish baseline ocular function and findings. All patients receive counselling in glaucoma, the disease, what it means and the therapy. Each patient is then randomised (randomisation in London, contained in sealed opaque envelopes) to receive SLT or prostaglandin analogue therapy. Every effort is made to follow all patients according to a standardised protocol at a minimum of 3, 6 and 12 months. All therapeutic failures are followed closely to ascertain further management plans and subsequent therapeutic compliance. Follow-up is offered beyond 12 months.

Follow-up:

1. At 3 months: Patients will have a structured questionnaire relating to any adverse effects from the therapeutic interventions. They will receive an examination of visual function, external ocular structures and intraocular pressure in addition to the optic nerve head. Those with

unacceptable topical/systemic side effects and those with partial or complete failure of IOP control (see outcomes) will have secondary therapy commenced in the form of timolol 0.5% or, if contraindicated, either brimonidine or oral acetazolamide)). The secondary therapy will either replace or be additive to the primary therapy depending on the initial response.

2. At 6 months: Patients will have a structured questionnaire relating to any adverse effects from therapeutic interventions. They will receive an examination of visual function, external ocular structures and intraocular pressure in addition to the optic nerve head. Those with unacceptable topical/systemic side effects and those with partial or complete failure of IOP control (see outcomes) will have secondary or tertiary therapy commenced in the form of timolol 0.5% or, if contraindicated, either brimonidine or oral acetazolamide)) or surgical intervention in the form of a trabeculectomy with cytototoxic.

3. At 12 months: Patients will have a structured questionnaire relating to any adverse effects from therapeutic interventions. This questionnaire will also include questions relating to their acceptance of the therapy and view of the therapy. They will receive a detailed examination of visual function and ocular parameters. Those with unacceptable topical/systemic side effects and those with partial or complete failure of IOP control (see outcomes) and those with evidence of glaucoma progression will have secondary or tertiary therapy commenced in the form of timolol 0.5% or, if contraindicated, either brimonidine or oral acetazolamide)) or surgical intervention in the form of a trabeculectomy with cytototoxic.

Intervention Type

Device

Primary outcome measure

Intraocular pressure reduction at one year. A reduction of 30% or more at one year is complete success and a reduction of 15-29% is partial success. In addition the proportion with an IOP less than 21, less than 17 and less than 14mmHg will be assessed as measured using Goldmann tonometry.

Secondary outcome measures

1. Visual function assessed as change in logMAR acuity
2. Progression of lens opacity assessed as change in LOCS III score
3. Reintervention rate- number experiencing reintervention during first year post commencement of therapy
4. Reintervention acceptance – number accepting reintervention during first year post commencement of therapy
5. Compliance – this is being assessed by weighing bottles prior to issuance and on return to the pharmacy for receipt of the next round of therapy (the difference in weight represents the number of drops administered from the bottle and will be compared to the number of doses that should have been taken during the period)
6. Compliance via a questionnaire to both patients and clinician
7. Complications – number of adverse events during the first year of therapy

Overall study start date

11/02/2014

Completion date

30/11/2018

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Consent to inclusion and participation in trial
2. Characteristic glaucomatous changes in the optic disc. The presence of a focal or diffuse area of optic disc rim loss, so that the neuroretinal rim tissue in any quadrant is less than 5% of the disc diameter in that meridian. Extensive loss of neuroretinal rim tissue with marked optic disc cupping giving a cup disc ratio greater than 0.6
3. A measured intraocular pressure greater than or equal to 21 mmHg and less than or equal to 30mmHg on at least one visit before the time of entry into the study as measured by Goldmann applanation tonometry
4. Adequate visualization of angle structures (i.e. clear media and cooperative patient)
5. Black African patients

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

A total sample size of 571 patients would be recruited (giving 400 followed-up at one year).

Key exclusion criteria

1. Unwillingness to participate in the study
2. Inability/unwillingness to give informed consent
3. Unwillingness to accept randomisation
4. Patient less than 20 years of age
5. Anterior segment neovascularisation
6. Past trauma to the eye or ocular adnexae
7. Retinal or optic nerve neovascularisation
8. Aphakia or pseudophakia
9. Previous ocular surgery Evidence of ocular disease other than glaucoma that might affect the measurements of IOP, assessment of visual function, visual field testing would likely require cataract surgery within 12 months of randomization on systemic medications known to -IOP (e.g. steroids) Pregnancy or female of childbearing age who may be pregnant at time of treatment (LMP).
10. Anyone who is not Black African race

Date of first enrolment

11/02/2014

Date of final enrolment

30/11/2017

Locations

Countries of recruitment

Kenya

South Africa

Study participating centre

Inkosi Albert Luthuli Central Hospital

800 Bellair Rd

Durban

South Africa

Private Bag X 03 Mayville, 4058

Study participating centre

Innovation Eye Centre

Kisii Eye Hospital

Kisii

Kenya

PO Box 1250

Sponsor information

Organisation

University College London

Sponsor details

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Sponsor type

University/education

Website

www.uclh.nhs.uk; www.ucl.ac.uk

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

International Glaucoma Association (UK)

Results and Publications

Publication and dissemination plan

Intention to publish the findings of the RCT 6 months following last data collection. Subsequent publications will include a paper exploring compliance in more depth and other secondary outcomes if indicated.

Intention to publish date

30/06/2018

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request