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

Submission date
13/12/2015

Recruitment status
No longer recruiting

Registration date
14/12/2015

Overall study status
Stopped

Last Edited
01/12/2020

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 and 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 cytotoxic.
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 cytotoxic.

Intervention Type
Device

Primary outcome(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed

No

Age group
Adult

Sex
All

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

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
International Glaucoma Association (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes