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A feasibility study of different types of laser to treat glaucoma in Nigeria

Submission date
05/03/2021

Recruitment status
No longer recruiting

Registration date
11/03/2021

Overall study status
Ongoing

Last Edited
08/10/2024

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Glaucoma is a group of eye diseases that result in damage to the optic nerve and cause vision loss. Laser treatment has become one of the first-line treatments for patients with glaucoma around the world. Selective laser trabeculoplasty (SLT) has been found to be effective in reducing intraocular pressure (fluid pressure inside the eye) around the world and in a few studies in Africa, but it is relatively expensive. The aim of this study is to assess the effectiveness of SLT and other types of laser treatment, namely micropulse trabeculoplasty (MLT) and micropulse transcleral laser treatment (mTLT), in patients in Nigeria. This is a feasibility study and may lead to the design of a larger trial if the effectiveness of the lasers is established.

Who can participate?
Patients aged 18 and over with uncomplicated open-angle glaucoma and residual vision, living within 200 km of the study centre

What does the study involve?
Participants are randomly allocated to one of three treatment options where the ophthalmologist decides that laser is the treatment indicated for that patient. Treatment success is measured after 1 year.

What are the possible benefits or risks of participating?
The benefit will be the preservation of vision by reducing intraocular pressure, avoiding the need for topical medication which is often unavailable or non-affordable and has low compliance. Risks are minimal as the laser doesn't cause destructive tissue damage. There may be some pain or mild inflammation which is routinely treated. In rare cases there may be complications leading to reduction or loss of vision.

Where is the study run from?
Abubakar Tafawa Balewa University (ATBU) Teaching Hospital (Nigeria)

When is the study starting and how long is it expected to last?
December 2018 to October 2025

Who is funding the study?
Velux Foundation (Switzerland)

Who is the main contact?
Dr Mohammed Abdull
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Proj. No. 1373

Study information

Scientific Title
Laser treatment for glaucoma in Nigeria: a feasibility study of four different treatment modalities to provide data to design randomised controlled trials

Study objectives
In Nigeria, where there are estimated to be 1.2 million adults aged ≥40 years with glaucoma, there is a considerable body of evidence which suggests that a high proportion of patients with glaucoma present with very advanced disease, but acceptance of trabeculectomy and

compliance with topical medication are very low. Patients are, however, more likely to accept laser treatment. There is, therefore, an urgent need to identify which is the most cost-effective form of laser treatment in this setting. The results of this evaluation will provide data that can help guide the design of randomized controlled trials comparing interventions for glaucoma in Sub-Saharan Africa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/02/2021, London School of Hygiene and Tropical Medicine (LSHTM) ethics and research committee (London School of Hygiene and Tropical Medicine, Keppel Street, London, WC1E7HT, UK; tel not known; ethics@lshtm.ac.uk), ref: 22040
Approved 09/12/2020, Abubakar Tafawa Balewa University Teaching Hospital Bauchi research and ethics committee (Abubakar Tafawa Balewa University Teaching Hospital, Hospital Road, Bauchi, Nigeria; +234 (0)8035044243; cchama1960@gmail.com), ref: 0048/2020

Study design
Randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
The researcher plan to use an online website to perform the randomisation (Sealedenvelope, https://www.sealedenvelope.com) in real time for each patient.

All patients recruited to the study will be randomised to either of the following three interventions in one or both eyes:
1. Selective laser trabeculoplasty (SLT)
2. Micropulse laser trabeculoplasty (MLT)
3. Micropulse transscleral laser treatment (mTLT)

If after a repeat treatment the IOP is not controlled they will be treated with transcleral diode laser cyclophotocoagulation (TDLC)

Intervention Type
Procedure/Surgery

Primary outcome measure
Success defined as intraocular pressure (IOP) at or below target (21 mmHg) on no IOP-lowering medication (complete success) or IOP at target on one or more medication (qualified success), measured at 1 year

Secondary outcome measures
Clinical:
1. Change in IOP (mmHg) at 12 months as a percentage of baseline IOP levels, measured using an Icare tonometer
2. Complications following the first, and subsequent laser treatment if needed, measured by a list and frequency of complications for each laser type after treatment or at follow up points: 1 week, 1, 2, 6 and 12 months
3. Number of individuals requiring repeat laser for each laser type expressed as a percentage, measured using records of repeat treatments at the end of the study
4. Pain score subjectively measured on a scale of 1-5 where 1 = pain and 5 = extreme pain, recorded immediately after each treatment
5. Visual loss (reduction of VA to <3/60 Snellen equivalent), attributable to glaucoma progression or other causes measured at 12 months

Non-clinical:
1. Recruitment rates: the proportion of eligible patients who consent to take part measured at the end of the study
2. Uptake of first and (where indicated) second or third laser treatments: the proportion of eligible patients who agreed to have the laser treatment measured at the end of the study
3. Follow up rates: the proportion of patients who return for follow up at 12 months
4. Patient-reported outcome measures (POEM) measured using a standard POEM questionnaire at 1 week after the first treatment

Overall study start date
17/12/2018

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Diagnosis of primary open-angle glaucoma (ISGEO category 1 & 2)(41) or Disc Damage Likelihood Scale (DDLS) grades 5-10
3. IOP >21 mmHg with or without glaucoma medication
4. Visual acuity better than 3/60 in eye(s) to be treated
5. Patient lives within 200 km of the hospital, for ease of follow up

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
480

Key exclusion criteria
1. Visual acuity ≤3/60 due to glaucoma or other ocular pathology
2. DDLS <5
3. History of glaucoma surgery or laser
4. Evidence or history of uveitis, trauma or neovascularisation, aphakia
5. Opaque cornea
6. Angle grading <Shaffer 2
7. Patient unable to give informed consent

Date of first enrolment
14/04/2021

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Nigeria

Study participating centre
Abubakar Tafawa Balewa University (ATBU) Teaching Hospital
Ophthalmology Department
Hospital Road
Off Yandoka Street
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

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Sponsor type
University/education

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ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Velux Stiftung

Alternative Name(s)
Velux Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
The protocol will be available but not published. The researchers plan to present their results at the World Ophthalmology Congress (WGC), The Ophthalmological Society of Nigeria (OSN)

annual conference, the International Society of Geographical and Epidemiologic Ophthalmology (ISGEO), The West African College of Surgeons annual conference and sister teaching hospitals in Nigeria.

Intention to publish date
14/10/2026

Individual participant data (IPD) sharing plan
Anonymised data collected can be shared with the consent of Dr Abdull Mohammed Mahdi, Professor Clare Gilbert and Dr Winnie Nolan. The full extent of what can be shared and for what will be determined by the group upon request. Dr Abdull Mohammed Mahdi will be the contact person at abdullmm@atbu.edu.ng.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/04/2021	No	Yes