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Treatment of Advanced Glaucoma Study

Submission date 13/01/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/01/2014	**Overall study status** Ongoing	
Last Edited 18/09/2024	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Glaucoma is a disease of the eye that occurs when the pressure of the fluid inside the eye is too high. It usually affects both eyes, although one may be more severely affected than the other. Glaucoma is very common; around 2% of the UK population over the age of 40 have the condition. This rate increases as people get older and as many as 10% of those in their 80s are affected. Glaucoma is the second most common reason for registering people as visually impaired in the UK. People with advanced glaucoma (those who have more severe visual field loss) have an increased risk of further progression and blindness. Glaucoma is most commonly treated by using eye drops (medical) or by an operation (surgery) to lower eye pressure. The aim of the study is to compare two methods of lowering eye pressure in patients with advanced glaucoma: an operation called a trabeculectomy, which allows the fluid to leave the eye more easily, and medical care, which may require up to four different eye drops to be used.

Who can participate?
Adults who have been diagnosed with advanced glaucoma in one or both eyes can participate.

What does the study involve?
Patients will be randomly allocated to either surgery or medical management provided that their ophthalmologist (eye specialist) agrees that either treatment is suitable and patients have consented. All participants will be asked to complete assessment questionnaires at certain time points - before treatment and again at about 1, 3, 6, 12 and 24 months after joining the study. Patients will usually undergo surgery (trabeculectomy) within 8 weeks of being listed for surgery. The surgery involves making a small hole in the eye and is usually done as a day case procedure (but may require hospital admission). It can be done under either a local or a general anaesthetic. Surgery normally takes about 40-60 minutes to complete. If both eyes need surgery, there will usually be a wait of around two to three months between the first and second operations. While waiting for surgery patients will be treated with eye drops to lower the eye pressure. Patients receiving medical management will be started on one or more medication(s) at their first hospital visit. The hospital doctor will decide what type(s) of eye drops are needed. The medications received may change at a later time if the hospital doctor thinks more treatment is needed. If eye drops do not control eye pressure it is normal for surgery (trabeculectomy) to be undertaken. Participants will also be asked to come back to an outpatient clinic at the treating hospital to check how they are getting on at around 4, 12 and 24 months after joining the study.

What are the possible benefits and risks of participating?
We do not think that there are any additional risks or disadvantages to participating in this study. Whichever group participants are allocated to, their care will be overseen by an experienced consultant ophthalmologist (eye specialist) and any surgery performed will be done by a trained and experienced glaucoma specialist. Steps are always taken to make sure that any possible risks are minimised. As part of routine care, participants will be well informed of potential risks.

Where is the study run from?
This study is being co-ordinated by the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen (UK).

When is the study starting and how long is it expected to run for?
Recruitment will start in the spring of 2014 and the funding will end in early 2020.

Who is funding the study?
National Institute for Health Research (NIHR), UK.

Who is the main contact?
Centre for Healthcare Randomised Trials
chart@abdn.ac.uk

Study website
http://www.tagsstudy.co.uk

Contact information

Type(s)
Scientific

Contact name
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Department of Ophthalmology
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13OY008

Study information

Scientific Title
Treatment of Advanced Glaucoma Study (TAGS): a multicentre randomised controlled trial comparing primary medical treatment with primary trabeculectomy for people with newly diagnosed advanced glaucoma

Acronym
TAGS

Study objectives
Primary medical treatment will produce better clinical outcomes, better patient-reported outcomes and be more cost effective than primary surgery in patients presenting with advanced glaucoma in at least one eye.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/12/2013, East Midlands - Derby (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8210; derby.rec@hra.nhs.uk), ref: 13/EM/0395

Study design
Pragmatic multicentre randomized controlled 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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Adults with advanced glaucoma

Interventions
The interventions being compared are: 1. primary trabeculectomy; 2. primary medical treatment

1. Primary trabeculectomy: participants randomised to trabeculectomy will receive the standard trabeculectomy augmented with mitomycin-C. The definition of standard trabeculectomy is creation of a 'guarded fistula' by making a small hole in the eye which is covered by a flap of partial thickness sclera and which allows aqueous humour to egress from the eye into the subconjunctival space. The operation may be performed under either local or general anaesthetic and normally takes about 40-60 minutes to complete.

2. Primary medical treatment: participants randomised to medical management can be prescribed a variety of currently licenced glaucoma drops. These drops will be used in accordance with NICE guidelines. The definition of escalating medical treatment is study participants may be started on one or more medications at their initial visit depending upon the judgement of the treating clinician. When monotherapy is initiated this should be with a prostaglandin analogue as directed by NICE guidelines; subsequent addition of medications is based on clinician judgement/preference. When drops fail to control intraocular pressure (IOP) adequately oral carbonic anhydrase inhibitors may be used.

It is impossible to mask the patient or those measuring outcomes to the intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measure as of 18/09/2024:
Patient-reported vision-specific health profile (NEI-VF Q25) evaluated at 2, 5 and 10 years

Previous primary outcome measure:
Patient-reported vision-specific health profile (NEI-VF Q25) evaluated at 24 months

Secondary outcome measures
Patient-centred:
1. Patient-reported health status as measured by EQ-5D (5-level), Health Utilities Index (HUI-3), Glaucoma Utility Index (GUI), National Eye Institute Visual Function Questionnaire (NEI-VF Q25)
2. Patient experience

Clinical:
1. Visual field mean deviation (MD) changes
2. Intraocular pressure (IOP)
3. LogMAR visual acuity change (LVA)
4. Need for cataract surgery
5. Visual standards for driving
6. Registered visual impairment
7. Safety

Economic:
1. Incremental costs to NHS, personal social services and patients
2. Incremental quality-adjusted life-years (QALYs) based on responses to EQ-5D, HUI-3 and glaucoma utility index

Overall study start date
01/01/2014

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Severe glaucomatous visual field loss (Hodapp classification) in one or both eyes at presentation
2. Open angle glaucoma including pigment dispersion glaucoma, pseudoexfoliative glaucoma and normal tension glaucoma
3. Willingness to participate in a trial
4. Ability to provide informed consent
5. Adult ≥18 years
6. Female participants of childbearing potential and male participants whose partner is of childbearing potential must be willing to ensure that they or their partner use effective contraception during the study and for 3 months thereafter. A negative urine pregnancy test for females of childbearing potential is required prior to randomisation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
440

Total final enrolment
453

Key exclusion criteria
1. Inability to undergo incisional surgery due to inability to lie flat or unsuitable for anaesthetic
2. High risk of trabeculectomy failure such as previous conjunctival surgery or complicated cataract surgery
3. Secondary glaucomas and primary angle-closure glaucoma
4. Females who are pregnant, nursing or planning a pregnancy or females of childbearing potential not using a reliable method of contraception. A female is considered to be of childbearing potential unless she is without a uterus or is post-menopausal and has been amenorrheic for at least 12 consecutive months

Date of first enrolment

03/06/2014

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Ophthalmology
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
Nottingham Integrated Clinical Research Centre
C Floor, South Block
QMC Campus, Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

Website
http://www.nuhrise.org

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) - NIHR Health Technology Assessment Programme - HTA (UK), ref: 12/35/38

Results and Publications

Publication and dissemination plan
Protocol at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/123538/#/

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the CI - Hon Prof Anthony J King (anthony.king@nottingham.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/07/2018	02/04/2019	Yes	No
Results article	results	01/05/2020	03/02/2020	Yes	No
Results article		12/05/2021	17/05/2021	Yes	No
Results article		01/11/2021	03/12/2021	Yes	No
Results article	24 month follow up	03/01/2023	04/01/2023	Yes	No
Results article	5 year results	08/01/2024	11/01/2024	Yes	No