

Treatment of Advanced Glaucoma Study

Submission date 13/01/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/01/2014	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/09/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

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

Contact information

Type(s)

Scientific

Contact name

Dr Anthony King

Contact details

Department of Ophthalmology
Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH

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Anthony.King@nottingham.ac.uk

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 amenorrhic for at least 12 consecutive months

Date of first enrolment

03/06/2014

Date of final enrolment

31/05/2017

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Ophthalmology

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Nottingham University Hospitals NHS Trust (UK)

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

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?
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
Protocol article	protocol	01/07/2018	02/04/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes