Participant Information Sheet
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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.

PART 1

1. Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

PART 1 tells you the purpose of this study and what will happen to you if you take part.

PART 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

BACKGROUND TO THE CONDITION

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 treated by using eye drops (medical) or by an operation (surgery) to lower eye pressure.

The two methods of lowering eye pressure that we will investigate in the TAGS study are:

- 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.

2. What is the purpose of the study?

Reducing pressure is currently the only effective treatment for glaucoma. Both the treatments described above are commonly and successfully used in the NHS to reduce pressure but we do not know which treatment is better to prevent patients with advanced glaucoma from losing further vision. In the TAGS study we aim to find out which option is best. We will recruit 440 participants from NHS hospitals throughout the UK. The study will help us to find the best treatment of patients with advanced glaucoma in the future.

3. Why have I been invited to take part?

You have been chosen because you have been diagnosed with advanced glaucoma in at least one of your eyes and treatment is required to lower your eye pressure to prevent further visual loss.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part.

If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to show that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

If you leave the study, we will still keep records about the treatment given to you, unless you object, as these are valuable to the study. If you decide to leave the study at any time, or decide not to take part, the quality of care you receive will not be affected.

5. What will happen if I take part?

Patients who agree to take part in TAGS will be given either medical (eye drops) or surgical (trabeculectomy) treatment. The particular treatment given to each person in the study will be decided by a computer system. This is called randomisation. Randomisation is similar to tossing a coin to decide which group you are entered into and is important to make sure that the results of the study are accurate.

If you decide to take part, neither you nor your doctor can decide which treatment you will receive. There is an equal chance you will be placed into either treatment group.

If you are happy to take part in the TAGS study you will be asked some questions to make sure that your circumstances mean you are suitable to take part in the study. If you are suitable, you will be asked to sign a consent form and complete the first questionnaire. Your details will be entered into a computer system and you will be allocated to receive one of the two treatment procedures. The doctors and nurses treating you will not be involved in your procedure allocation and have no control over what group you are put in. Both procedures are suitable for the treatment of your glaucoma and are currently used in the NHS.

You can find further information about the two treatments in section 7.

6. What do I have to do?

To collect the information we need, everyone in the study will be sent questionnaires by post approximately 1, 3, 6, 18 and 27 months after you join the study. The questionnaires ask about your vision and general health.

We will send you up to two reminders and will aim to contact you by post, email and/or telephone, taking into account which communication method is best for you. If you are in the surgery group we will ask you to complete another questionnaire before your operation.

After your treatment you will be asked to come back to an outpatient clinic at your hospital to check how you are getting on. We will ask you to complete questionnaires about your vision while you are in the clinic at around 4, 12 and 24 months after you join the study; we will also collect information about your treatment at these visits. Participating in this clinical trial will not affect the care you receive for your glaucoma

All the clinical care that you receive during the study will be the same as the standard care that is usually given within the NHS.

In addition to collecting information about your clinical condition we will also collect information about your income and what you spend in relation to your glaucoma care. This information is important as it will allow researchers to determine which treatments are best value for money. You may decline to provide this information if you wish

The study nurse and/or doctor involved in the study will also collect information from your NHS records during the time you are in the study.

Glaucoma is a lifelong condition and we want to make sure that the treatments we give have a long-term benefit. To this end, we aim to apply for funding to extend this study so we can look at longer-term outcomes (up to 10 years from when you started participating in the study). If this extension is funded we would like to continue to include you in the study for this longer period. We will use the same questionnaires that are currently used in this study, which we will ask you to complete every couple of years at most. We would also collect information from your medical records about your eye health and your glaucoma treatment. This will not require any extra visits to hospital clinics for you as your glaucoma will continue to be treated in the NHS for the rest of your life and the information we will be collecting will be part of your routine care.

Data for all participants in the study, including those who withdraw, will be kept securely for a minimum of 15 years.

7. What are the treatments being tested?

Group name	Procedure
Eye drops	• You will be started on one or more medication(s) at your first hospital visit. Your doctor will decide what type(s) of eye drops you need. • The medications you receive may later change if your doctor thinks you need more treatment for your glaucoma • If eye drops do not control your eye pressure it is normal for surgery (trabeculectomy) to be undertaken
Trabeculectomy	• This will happen within 3 months • Involves making a small hole in your eye • Day case procedure (but may require hospital admission) • Can be done under either a local or a general anaesthetic • Surgery normally takes about 40-60 minutes to complete • If both your eyes need surgery, there will usually be a wait of around two to three months between your first and second operations. • While waiting for surgery you will be treated with eye drops to lower the pressure

Waiting times for treatment will reflect current care in the NHS and we expect the procedure will be carried out in around three months of you agreeing to take part. Individual patient needs will be taken into consideration.

8. What are the alternatives for diagnosis or treatment?

Eye drops or trabeculectomy are the two most common treatments for people with advanced glaucoma. Laser treatment can also be used to treat glaucoma but is not often used to treat patients with advanced glaucoma.

9. What are the side effects of any treatment received when taking part?

If you do decide to take part in the study, you must report any problems you have to your study nurse or doctor. There is also a contact number

given at the end of this information sheet for you to phone if you become worried at any time.

There are no expected risks or disadvantages to participating in TAGS. Whichever group you are allocated to, your care will be overseen by an experienced consultant ophthalmologist (eye doctor) 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, you will be well informed of potential risks.

<u>The reported side effects of eye drops include:-</u>

Common (greater than 1 in 10)
Redness*
Stinging*
Itching*
Transient blurred vision
Eyes watering*
Ocular discomfort*

Occasional (between 1 in 10 and 1 in 50)
Allergy*
Eyelash growth
Change in skin colour around eye
Change in iris colour
Shortness of breath
Unpleasant taste in mouth
Dry mouth

Uncommon (less than 1 in 50)
Fatigue
Kidney stones
Skin rash
Cataract formation
Retinal detachment

* In some case these symptoms may be due to preservatives in the drops – if this is the case preservative free drops can be used.

Reported trabeculectomy side effects include:-

Common (greater than 1 in 10)
Discomfort
Blurred vision
Cataract formation within 5 years

Occasional (between 1 in 10 and 1 in 50)
Pressure too low
Leak from operation site

Uncommon (less than 1 in 50)
Infection
Severe loss of vision (less than 1 in 500)
Bleeding in the eye

Both surgery and medical treatments are often used in the NHS for treating glaucoma patients. Although all these complications are well-recognised, many patients do not suffer any problems and most of the side effects are mild.

10. What are other possible disadvantages and risks of taking part?

For Women:
The eye drops might harm an unborn child; therefore you should not take part in this study if you are pregnant, breast-feeding or you intend to become pregnant during the study. If you are a woman who could become pregnant, you will be asked to have a pregnancy test (urine) before taking part.

To take part in TAGS you must agree to use a reliable form of contraception during the trial (if taking eye drops). This should be continued for at least three months after the treatment has finished.

11. What are the possible benefits of taking part?

We cannot promise the study will help you but by taking part in this study you will be directly helping us to inform the treatment of future patients diagnosed with glaucoma. The results of the study will help plan effective services offered by the NHS.

You will receive the same health care from your doctors whether you choose to participate in the study or not.

12. What happens when the research study stops?

Your doctor will continue your care and treatment as standard. If the study is stopped earlier than expected for any reason, you will be told and your continuing care will be arranged

13. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details are available from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

14. Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. Details are included in Part 2.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read Part 2 before making any decision.

PART 2

15. What if new information becomes available?

Sometimes during the course of a clinical trial, new, relevant information becomes available on the treatments that are being studied. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign a new consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

16. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, but you will need to continue attending appointments with your ophthalmologist and/or optometrist to have your glaucoma monitored as part of your standard care. It is normal that your glaucoma will be monitored for the rest of your life.

17. Will my part in this study be kept confidential?

If you consent to take part in this study, your records will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital and the registered clinical trials unit (CHaRT) managing this research under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

Information will be transferred from your hospital site to the clinical trial centre (CHaRT) organising the research, to enable questionnaires to be sent to you and analysis of the study results. This will be done by mail and electronically. Personal details like your name and address will be sent separately to any clinical results collected for the trial. All other records will have your name removed and will only feature your unique study number and date of birth.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

If you withdraw consent from further study treatment, unless you object, your data will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study.

Other researchers may wish to access data from this study in the future (this will not include names, addresses or dates of birth, and it is not possible to identify participants from the data). If this is the case, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

18. Informing your General Practitioner (GP)

If you participate in the study we will tell your GP you are taking part, but only with your permission. We will also ask your GP to contact us if you visit them with any problems that may relate to your glaucoma treatment.

19. What will happen to any samples I give?

We are not taking any samples as part of this study

20. Will any genetic testing be done?

No, there is no plan to undertake genetic testing

21. What will happen to the results of this clinical trial?

The results of the study will be used to make recommendations on treatments for patients with advanced glaucoma. The results of this study will also be published in scientific journals and presented at scientific meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

22. Who is organising and funding this clinical trial?

The study has been designed by UK ophthalmology medical doctors and researchers. Patients will be recruited at different hospitals throughout the UK. The Nottingham University Hospitals NHS Trust will act as sponsor for the research.

The study is being funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme. It

is being co-ordinated by The Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered clinical trials unit, at the University of Aberdeen.

23. **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the NHS by Derby 1 Research Ethics Committee.

The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust and of your local Research and Development Office.

24. Contact for further information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact the local study team whose contact information is given at the end of this Patient Information Leaflet.

For further information about trabeculectomy surgery the International Glaucoma Association provides a "glaucoma buddy" service where it is possible to speak to a patient who has previously undergone trabeculectomy and will discuss the surgery with you. This service can be accessed through the IGA Sightline Service at 01233 648170.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and for considering this study.

If you have any questions or would like any more information, please contact:

Study Office contact details:

TAGS Study Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen AB25 2ZD

Telephone: *+44 (0)1224 438196*

Email:*tags@abdn.ac.uk*

Website:*http://www.tagsstudy.co.uk*

Local contact details:

<<Insert contact details of local PI and/or Research Nurse>>

<<Insert contact details of local patient advice and liaison service>>