**LASER TREATMENT FOR GLAUCOMA IN NIGERIA:**

**feasibility study of four different treatment modalities to provide data to design randomised controlled trials**

**INFORMATION SHEET FOR ELIGIBLE PATIENTS**

**Introduction**

Glaucoma is a common eye condition in Nigeria, which can cause blindness. It usually affects both eyes and leads to gradual, painless loss of vision due to damage to the nerve at the back of the eye which carries information from the eyes to the brain.

Glaucoma cannot be prevented, but treatment can prevent people from becoming blind. There are several different types of treatment for glaucoma, and the eye doctor has recommended that you have laser treatment. This treatment uses a special kind of light which reduces the pressure inside the eye, which prevents further damage to the nerve and preserves vision.

We are carrying out a study to find out which is the best type of laser for patients with glaucoma in Nigeria. We are using lasers that are already being used in other parts of the world. The findings of this study will help other people who have the same eye condition as you in the future. Your participation is therefore very important.

**Why have I been selected to take part in the study?**

You have been approached to take part in this study because you have glaucoma and the eye doctor at ATBUTH has recommended that laser treatment may work well for you.

**What will happen if I take part in the study:**

Firstly, we will ask you a few questions about glaucoma and how you are feeling and coping. Then you will then be randomly allocated by computer to one of three different types of laser treatment. We will try our best to conduct the treatment today. The treatment will either be given either in a special room in the eye clinic or you will be treated in the operating theatre. If you are treated in the eye clinic some drops will be put in your eye or eyes to numb them, and you will be treated sitting in front of the equipment we usually use to examine patients eyes. The treatment is relatively painless and take less than 15 minutes. If you are treated in the operating theatre the same eye drops will be put in your eye or eyes. For this treatment you will be lying down, and a bright light will be shone into your eye or eyes to we can see your eyes clearly. This treatment is also relatively painless and take less than 15 minutes. Whichever treatment you have you will not need to stay in the hospital. Whichever type of laser treatment you are given, only very experienced eye doctors will treat you.

After the treatment the doctor will instruct you what to do. You will be asked to come back for a check-up after one week, then at 1, 4, 6 and 12 months. It is very important that you attend on all the dates given to you after this treatment so we can monitor your progress.

If the pressure in your eyes is still high at any of the follow up visits you will be offered further laser treatment. This will either be a repeat of the first type of laser, or you will be offered eye drops and the fourth type of laser, which will be done in the operating room, with an injection around the eye to make the treatment painless. If the doctor prescribes eye drops you will need to use them every day. Your doctor will explain all of this to you.

**Inconvenience and discomfort**

You may experience some discomfort, as the eye drops used before the laser treatment can cause an initial stinging sensation but this quickly goes as the eyes become numb. If you are offered treatment in the operating room, the injection can cause some initial pain, but this goes away as your eye becomes numb.

There may be some discomfort after the procedure as your eye or eyes may become red and or mildly painful, but these are temporary. You will be given medication to relieve these symptoms, if needed. You may also notice that your vision is a bit blurred and your eyes are a bit red immediately after the treatment, but this usually gets better after a few hours. However, if it the redness and blurring of vision persist this may point to more serious complications, and you should return to the hospital. The doctor will examine your eyes and further treatment will be given, as needed. More serious side effects, although rare are still possible. These may include severe pain, sudden or severe loss of vision, swelling around the eye, difficulty opening the eye, or a soft eye.

Be assured that every possible precaution will be taken to prevent these serious adverse effects, by following the protocol exactly. If these complications do occur, you must return to the hospital where you will be treated in the best possible way and at no expense to you.

**Confidentiality**

All information you provide will be kept secure and will only be seen by the research team. We will not use your name at any time in reports or when we present the results of the study. We may share your data with other researchers in the future but will ensure that you will not be identified.

**Financial arrangement**

If you cannot afford to pay for visits to the hospital for follow up your transport costs will be funded by the hospital. Please discuss this with one of the research team before agreeing to take part in the study.

**Right to refuse or withdraw from trial**

Participation is entirely voluntary: if you decide not to take part this will not influence the type of treatment you receive for your eyes in any way. You also have the right to withdraw from the study at any stage without giving a reason, and this will not affect the treatment you receive in the eye clinic.

Dr Abdull and his team at ABUTH eye clinic are working with experts at the London School of Hygiene and Tropical Medicine in the UK. The study has been approved by the authorities at ATBUTH and at the London School of Hygiene and Tropical Medicine.

**Investigator’s name and contact details**

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**CONSENT FORM**

You are free to discuss whether or not to take part in this study with family members or other people.

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| --- | --- |
|  |  **Circle one** |
| I have read the information sheet about the study/or it has been read out to me. I understand what will be required of me if I agree to take part in the study | Yes | No |
| My questions concerning laser treatment have been answered | Yes | No |
| I understand I may withdraw from this study at any time without having to give reasons and that this will not affect my normal care | Yes | No |
| I agree that the information collected about me during the study can be shared with researchers in future, but my name will not be mentioned. | Yes | No |
| Having heard all the necessary information and my questions answered I give consent to undergo laser treatment for my eye or eyes | Yes | No |
| I agree to take part in this study | Yes | No |

Name.........................................................................................Date …………………….....

Signature....................................................................................OR thumbprint

Independent witness confirming voluntary participation in presence of thumbprint

when signature not possible

Name......................................................................................Date……………

Signature……………………………………………………..

Signature of Project Manager/Witness......................................Date.........................................

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