Study of Technologies for the Diagnosis of Angle Closure glaucoma (ACE)

Patient Information Leaflet
IRAS ID: 315388

You are being invited to take part in this research study called: "Study of Technologies for the Diagnosis of Angle Closure glaucoma (ACE)"

Before you decide 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; do not hesitate to ask us questions if there is anything that is not clear.

Thank you for your time to consider participation in the ACE Study

What is the purpose of this study?

The purpose of ACE is to determine whether people referred by an optician with possible angle closure could be safely diagnosed by health care professionals other than eye doctors. Angle closure may put your eyes at risk of developing glaucoma.

Why have I been chosen?

You are being invited to take part in this study because your eyes may have angle closure.

Do I have to take part?

No, taking part is voluntary. If you decide to take part you will be given this information leaflet to keep and will be asked to sign a study consent form. If you decide not to take part in this study that will be alright and your care will not be affected.

What will happen if I decide to take part?

- Some information about you will be noted in our research records (for example information about your age, gender, postal code, prescription glasses, etc).
- For the purpose of this study we will obtain some images of the angle, at the front part of your eyes, (these will be anonymised) and you will be seen by an optometrist and by an eye doctor at the eye clinic.
- For the purpose of this study, you will be asked to fill in some questionnaires which will provide us with information about your quality of life.

It is possible that the images of the front part of your eyes may be used not just for this study but for other research studies in the future; nobody will be able to recognise you from the photographs.

We would also like to ask your permission to contact you in the future if we want to examine your eyes again for research purposes. If you decide not to consent to being contacted in the future, it will not have any influence on your involvement in this particular research study and will not affect any standard of care that you receive.

How will we use the information about you?

We will need to use information about you and your eyes for this research project. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are the possible inconveniences for me if I decide to take part on this study?

The only inconvenience is that you will have tests taken by different clinicians (optometrists and ophthalmologists) and you will need to fill in some questionnaires. This will add 15-20 minutes to your visit today.

What are the possible benefits to my taking part?

- You will be helping us to determine whether other health professionals besides eye doctors could look after people that have been referred to the eye clinic with angle closure.
- If we find that this is the case, this will relieve doctor's time in the NHS and doctors could then see patients with serious eye diseases and who require treatment more promptly.
- This may help you in the long term as this would potentially help with waiting times in the NHS.
- If the study shows that having other health professionals seeing patients once they are stable is not as good as having doctors evaluating them, then this strategy will not be implemented in the NHS.

Will my participation be kept confidential?

Any information collected about you during the course of the study will be kept strictly confidential and will only be seen by staff involved in the study from the NHS Trust, the Trial Co-ordinating Centre (Northern Ireland Clinical Trials Unit), Queen's University Belfast and people from regulatory authorities who ensure that studies such as this are carried out correctly. Personal information such as date of birth, gender and postcode, will be held by the Trial Co-ordinating Centre, all other personal data will remain anonymised. This information will be used only for this study and will not be given to anyone else.

This research will be conducted in compliance with data protection legislation. For more information about how we look after your information, how to access your rights and who to contact if you have any queries or concerns about data protection please visit the Queen's University Belfast website - www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipant

What will happen to the results of the research study?

Data from this research study will be published in a medical journal. Nobody will be able to identify you from any of the data/photographs published.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/,
by asking one of the research team, or
by sending an email to our Data Protection Officer, Ms Sandra McDonald, at: S.McDonald@qub.ac.uk or at: www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipant

Who is organising and funding this study?

The ACE study is sponsored by Queen's University Belfast. ACE is organised and led by Professor Augusto Azuara-Blanco, who is an honorary consultant ophthalmologist at the Belfast Health & Social Care Trust, Northern Ireland and a Clinical Professor at Queen's University Belfast. The ACE study is funded by a grant from the National Institute of Health Research (NIHR). The Clinical Trials Unit coordinating the study is the Northern Ireland Clinical Trials Unit (NICTU). Patients will be recruited from across the UK, as several hospitals in the UK are participating in this study.

Who has reviewed the study?

This research has been reviewed by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. Having reviewed the study, the Research Ethics Committee has given permission for the study to take place. The research office at your hospital has also reviewed and approved this study too.

What if I have any questions, concerns or complaints about the study?

If you have any questions about participation in this study or concerns about the way it has been carried out you should ask to speak to the researchers who will do their best to answer your questions.

What if something goes wrong?

There are no side effects of taking images of the front of your eyes.

What are the costs and payments for taking part in this study?

If there is an additional visit for taking part in this study the travel costs will be reimbursed. You will not be compensated for taking part in this study if it is done during your visit to the hospital eye service.

Who to contact for further information:

Contact Details

Principal Investigator:	*Update with local details*
Name:	«name»
Address:	«address»
Telephone:	«telephone»

Chief Investigator:

Name:	Professor Augusto Azuara-Blanco
Address:	Centre for Public Health, Queen's University Belfast Institute of Clinical Sciences-A (ICS-A), Grosvenor Road, Belfast, BT12 6BA
Telephone:	02890 976350
Email:	a.azuara-blanco@qub.ac.uk

ACE Trial Co-ordinating Centre:

Address:	Northern Ireland Clinical Trials Unit 7 Lennoxvale Belfast, BT9 5BY
Telephone:	028961 51447

Complaints/Concerns:	*Update with local details*
Name:	«name»
Address:	«address»
Telephone:	«telephone»