**Participant Information Sheet –**

**DiaGO (Diagnosis of Graves’ Orbitopathy) study**

We'd like to invite you to take part in our research study. It is entirely up to you whether you take part, but before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 5 minutes. The first part of this Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the conduct of the study.

**Summary of the research**

**Background**

Thyroid eye disease (TED) is an inflammatory condition of the eyes associated with Graves’ disease (the commonest cause of an overactive thyroid). TED is also known as Graves’ orbitopathy (GO). In its most severe forms, TED can cause blindness. The earlier TED is treated the better the results. However, recognising TED can be challenging for doctors and delays in diagnosis are unfortunately common. Through patient support groups, such as the British Thyroid Foundation and the Thyroid Eye Disease Charitable Trust, we have discovered that patients place a high importance on receiving a diagnosis and appropriate treatment early, and therefore this is a priority.

We have developed DiaGO, a clinical assessment tool, to guide doctors in making a possible diagnosis of TED in patients with Graves’ disease. DiaGO is a set of questions and a simple examination of the eyes that can be done quickly by health professionals. The DiaGO assessment tool has already been tested in a pilot study where we found that it can be used to accurately identify TED in patients with Graves’ disease whose eye condition was previously undiagnosed. Making a diagnosis means that these people can be referred to specialist ophthalmologists (eye experts) who can make an early diagnosis and offer specialist treatment when it is required.

**Study aims**

This current study aims to test the DiaGO clinical assessment tool on a larger scale, across multiple UK hospitals, so that we can determine whether it can be used widely in outpatient endocrinology clinics (where Graves’ disease patients are commonly seen regularly) to help detect TED in patients at an early stage.

**What the study involves**

The DiaGO assessment tool is made up of two sections. Participants in this study will be asked 13 simple (yes/no answer) questions from section one (which takes approximately 3 minutes), and then a doctor will look at the participant’s eyes and complete section two of the tool (which is made up of 7 further yes/no questions based on the appearance of the eyes). The doctor completing the examination then uses the tool to generate a score. The score can then be used to decide who should be referred to the eye specialists.

In the first phase of this study, patients scoring on DiaGO will be referred to ophthalmology for further review. These individuals will have signs and/or symptoms of TED and therefore this is part of their routine care. In the second phase of this study, all patients completing the DiaGO questionnaire will be referred to ophthalmology, regardless of their score. This is to see whether some people with TED are being missed by the DiaGO tool.

Those patients who are invited to attend ophthalmology will receive a separate appointment for this. This will therefore involve a separate visit to the hospital outpatient clinic and the examination will take approximately 30 minutes. This appointment involves the ophthalmologist looking at the eyes in detail. This examination is not painful. If there is any evidence of TED, treatment may be offered if it is required.

**Who is included**

This study is open to patients who have Graves’ disease who are 18 years of age or older. People already known to have TED are not being included in our study.

This study is taking place in 5 sites: Newcastle upon Tyne, Cardiff, Edinburgh, Leeds and Exeter. The study is due to begin in January 2016 and end in January 2017.

**Advantages and Disadvantages of taking part in the DiaGO study**

TED is a much feared complication of Graves’ disease. Participants in phase two of the study will have the opportunity to see an ophthalmologist, regardless of whether they have any eye symptoms or not, which they may find reassuring. Participants found to have evidence of TED will be offered early treatment when it is needed.

The disadvantage of participating in the DiaGO study is that, in phase two of the study, you will need to come to hospital for an additional outpatient appointment to have an ophthalmology assessment. If you have no eye symptoms or signs suggesting TED, this is unlikely to benefit you.

**Do you have to take part in this study?**

No. You are under no obligation to take part in this study. If you do not wish to take part, your ongoing clinical care will not be affected in any way.

**Further Information**

**Withdrawing from the study**

Participation in this study is entirely voluntary, and you may change your mind at any time. If you withdraw from the study, we will use the data collected up to your withdrawal and your further care will not be affected.

**Confidentiality**

Data collected in this study will be anonymised at each participating centre. Your individual data will be given a study code and therefore you will not be identifiable individually. We plan to publish the overall study results in a medical journal.

**Study funding**

This study is being funded by a research grant from the charities Fight for Sight and Thyroid Eye Disease Charitable Trust. It is being sponsored by the Newcastle upon Tyne NHS Hospitals Trust.

**Patient and Public involvement**

Patient and public involvement events are now shaping research in TED. Patients tell us that prevention of TED and earlier diagnosis is a priority and this information has shaped this research study. Members of two patient support groups (The British Thyroid Foundation and the Thyroid Eye Disease Charitable Trust) have been involved in developing the DiaGO clinical assessment tool.

**Ethical approval for the DiaGO study**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Research Ethics Committee.

**Concerns and complaints**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the hospital Trust in writing. Details can be obtained locally from the study leads at each participating centre.

For independent advice regarding participating in research studies you can contact the Patient Advice and Liaison Service (PALS).

In the Newcastle upon Tyne Hospitals Trust, PALS can be contacted on:

**Freephone: 0800 0320202**
**Text: 01670 511098**
**Email:** **northoftynepals@nhct.nhs.uk**

**Contact information**

Key contacts at each participating site include:

* Dr Petros Perros, Department of Endocrinology, Royal Victoria Infirmary, Newcastle upon Tyne, Newcastle. Email petros.perros@nuth.nhs.uk
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