COMBAT

Local Trust Headed Paper

Clinical- and cost-effectiveness, safety, and acceptability of COMBined phacovitrectomy, versus sequentiAl viTrectomy and cataract surgery, for the management of rhegmatogenous retinal detachment: A Randomised Equivalence Clinical Trial

Short title: COMBAT

PARTICIPANT INFORMATION LEAFLET

You are being invited to take part in this research study which, in short, we call COMBAT.

Before you decide to take part, it is important that you understand why this research is being done and what will it mean for you to take part in it. Please take time to read the following information and discuss it with your doctor, family, and friends, if you wish. Do not hesitate to ask us questions, if you have any.

And for you to understand, we would like to clarify, first, the meaning of:

Phacovitrectomy: To have cataract surgery and the surgery to the back of the eye to repair the retinal detachment, both at once.
Vitrectomy: This is the surgery that will be used to repair your retinal detachment.

What is the purpose of this study?

The retina is the layer at the back of the eye that gives sight. Normally it is attached to the wall of the eye, but it can separate in a condition called rhegmatogenous retinal detachment (RRD). RRD causes sight loss and requires surgery.

The most common surgery to treat RRD is vitrectomy. Depending on how bad the RRD is, a single operation may put the retina back in place in around 8 in 10 eyes.

Vitrectomy can have complications. The most common is cataract. A cataract is when the lens of the eye, normally clear, becomes foggy. Cataracts often get worse with time. When they affect vision, they need to be removed with surgery. In cataract surgery, the foggy lens is replaced with an artificial clear lens. Patients with RRD may already have an early cataract, especially if they are older than 50 years. Surgeons do not routinely offer cataract surgery at the same time as vitrectomy in people with RRD. So, most often, when the cataract gets worse after the vitrectomy, cataract surgery is offered at that time.

COMBAT will test whether it is better to continue to do the vitrectomy alone when repairing the RRD or whether it may be better to do both the cataract surgery and the vitrectomy surgery at the same time, in one single operation.

<u>Potential</u> advantages of doing cataract surgery and vitrectomy at the same time are:

- Taking out the cataract may make it easier to fix the RRD.
- If the cataract is removed at the time of the retinal detachment repair, people will not lose their sight later, after the retina is put back in place, because of the cataract.
- The patient has one operation rather than two.
- The patient may need fewer hospital visits.

<u>Potential</u> disadvantages of doing cataract surgery and vitrectomy at the same time are:

- Choosing the artificial lens may be less accurate in an eye with a RRD affecting the centre of the retina (the so called “macula off” RRD), meaning that more people may need glasses after surgery.

- The operation is likely to take longer.
- The patient may have more inflammation in the eye.

Potential advantages of doing cataract surgery after vitrectomy:
- Choosing the artificial lens may be more accurate in an eye with a "macula off" RRD, meaning than less people may need distance or reading glasses after the surgery.
- The operation may take less time.
- There may be less inflammation after the surgery.

Potential disadvantages of doing cataract surgery after the vitrectomy are:
- Cataract surgery may be more difficult to do after the vitrectomy.
- Having two operations may be more expensive for the NHS.
- Patients may have extra costs of travel and time off work.

At the moment, we do not know for sure which are the **real** advantages and disadvantages of having cataract surgery and vitrectomy together in a single surgery or separately (vitrectomy first and then, later on, cataract surgery). The COMBAT study will help us to find out which option might be best for people with RRD.

Why have I been chosen?

You are being invited to take part in the COMBAT study because you have a RRD and you need a vitrectomy to try to put your retina back in place (i.e. to reattach it).

Do I have to take part?

No. It is voluntary and not taking part will not affect your care.

What will happen if I decide to take part?

The research team will provide you with more information about the study, explain the study in detail to you and answer any questions you may have. If you still wish to take part, you will be asked to sign a consent form.

If you agree to take part, you will be checked carefully by the research team and by a doctor and likely by your surgeon during the first visit before your surgery. Taking part in the COMBAT study will not delay your surgery.

Your previous medical and eye history will be reviewed. Then, your sight will be carefully checked. The back of your eye will be examined as well as your RRD. Measures of the size of your eye will be taken. You will be asked to answer some questions about how the RRD affects your quality of life.

When all these tests are completed, you will be ready to receive your surgery. The surgery will be one of the two options: 1) vitrectomy alone or 2) vitrectomy and cataract surgery in the same operation. The type of surgery you get will be determined randomly (i.e. by chance), by a computer.

At present time, most surgeons in the UK do not offer to their patients with a retinal detachment the possibility of having the cataract surgery at the same time as the retinal detachment repair (so, most patients are offered only the "vitrectomy" but not the "phacovitrectomy"). This is likely because, as we said above, we do not know at present time what is best to do.

Then, you will be seen about one week later and then around 6 weeks, 12 weeks and 52 weeks after the surgery. Your participation in the trial will then finish. All these visits, apart from the one at 12 months, will happen anyway, if you were not taking part in the COMBAT study because they are part of standard care.

At the one week visit you will probably have gas in your eye and not be able to see much. After that, at the later visits, you will have your sight measured carefully. At all visits after surgery, the back of your eye will be checked, and

we will ask you about your experience with the treatment you received, and we will ask you to fill in some questionnaires. This is to help us understand any anxiety, stress, pain, or other effects that the treatment has on you. Any complications that you may have had will be looked at, treated, if needed, and recorded.

You will be asked to keep a record of the costs of your attendance at hospital, so that we know the costs for people of each surgery.

If your surgery is not successful (i.e. the retina does not reattach) or if your retina re-attaches initially but then detaches again, further surgery will be offered to you and done if you agree. This is what happens currently to people with RRD in standard care in the NHS.

As part of the COMBAT study, we plan to organise individual interviews with a selection of participants in various places throughout the UK, to further understand how people feel about the treatments and their experiences. If you are interested in taking part in these interviews (you will take part in a maximum of 3 interviews in total), you will be contacted at a later stage about taking part and given further information and asked to provide your consent.

Not everyone that is being asked if they would be interested to participate in these interviews will be called to attend the interview. Participants will be selected from all those interested to take part to ensure we will have a diverse group of people providing their views.

What are the possible disadvantages to my taking part in the COMBAT study?

It is unlikely that you will be in disadvantaged if you take part in the study. The only thing is that you will need to come to hospital for the extra check-up at 52 weeks. Normally, in the NHS, we discharge people with RRD 12 weeks after surgery if they are doing well.

What are the possible benefits to my taking part?

By taking part in the COMBAT study, you may benefit yourself and others by helping us to determine the best treatment for people with RRD. If doing cataract surgery at the same time as the vitrectomy is found to be better or as good as vitrectomy alone, and is preferred by people with RRD and less costly to the NHS, this treatment (vitrectomy and cataract surgery) is likely to be offered to all people with RRD, which is not currently the case in the NHS.

In addition, if you take part in the COMBAT study, we will arrange for your check-ups to take place in a timely manner.

Will my participation be kept confidential?

Yes. Any information collected about you during the course of the study will be kept strictly confidential. Only the staff at your hospital and those involved in the COMBAT study from Queen's University Belfast, the Northern Ireland Clinical Trials Unit (Based in Belfast Health and Social Care Trust) and people from regulatory authorities (if required) who ensure that studies such as this are carried out correctly, will have access to it. They all have a duty of confidentiality to you as a research participant. If you agree, your GP will also be notified if you take part in this study.

If you express an interest in participating in the individual interviews, your name, address, contact details and demographic information will be provided to the researchers at Queen's University Belfast so that they can select people to invite to these interviews. This will allow us to ensure that we hear from a diverse group of patients affected by RRD.

The data from this study will be kept for at least 5 years after its conclusion by Queen's University Belfast, and the Northern Ireland Clinical Trials Unit, (Based in Belfast Health and Social Care Trust). The data may be shared

with others in and outside these institutions and used in other research studies, if you consent for this to happen. If it is used in this way, all personal identifiers will be removed, and it will not be possible to identify you. Once COMBAT is completed, and if you consent for this, members of the research team may review your medical records or contact your optometrist to obtain information about how you are doing, as part of a future study. This is to try to understand whether you needed other surgeries for your eyes in years to come.

What will happen to the results of the research study?

The results from the COMBAT study will be published, so that people with RRD across the world can benefit from what we learn. All data will be published anonymously and nobody will be able to identify the participants from any of the published data.

Who is organising and funding this study?

The COMBAT study is organised and led by Professor Noemi Lois, who is an Honorary Consultant Ophthalmologist and Vitreoretinal Surgeon at the Belfast Health and Social Care Trust and a Clinical Professor in Ophthalmology at Queen's University Belfast. The research is funded by a grant from the National Institute for Health and Care Research (NIHR). The Northern Ireland Clinical Trials Unit (NICTU), based in the Belfast Health and Social Care Trust, is the Trial Co-ordinating Centre. Queen's University Belfast is the sponsor.

Who has reviewed the COMBAT 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. The research office at your hospital has also reviewed and approved this study.

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

If you have any questions about taking part in this study or concerns about the way it has been carried out, you should contact your local Principal Investigator or a member of the research team at your hospital (contact details below). They will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the normal health service Complaints Procedure.

What if something goes wrong?

Every effort will be made to ensure that no-one taking part in the COMBAT study is put at risk or harmed in any way. Both treatments, vitrectomy alone and phaco-vitrectomy (which is when the cataract surgery is done at the same time as the vitrectomy) are used to treat people with RRD in the NHS. The risks of these surgeries will be the same if you take part in COMBAT or not.

In the unlikely event that something does go wrong, and you suffer harm as a result, you may have grounds for legal action, but you may have to pay your legal costs.

What happens if I do not want to carry on with the study?

You may withdraw from the COMBAT study at any time. We would be grateful if you could consider this decision carefully, but, if you wish to withdraw, you can do so without giving us a reason for your decision. If you decide to withdraw, we would be grateful if you could inform the research team as soon as possible about your decision to withdraw. You will

continue to receive care as would have happened if you had not joined the study. If you withdraw, only data collected up to the point of withdrawal will be used for the study.

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

If you take part in the COMBAT study, you will be given £30 for each study visit (when we check you at the start, surgery, 1 week, 6 weeks, 12 weeks and 52 weeks after the surgery) which will be given to you as cash or voucher, whatever you prefer. Please note that you will not receive money for any other additional visits.

If you would like to receive the study results, please let the study team at your hospital know and provide your contact details on the consent form. Your contact details will be used to provide you with a copy of the results at the end of the study.

Thank you for taking the time to read this information leaflet and for considering taking part in the COMBAT study.

Who to contact for further information:

Principal Investigator:	«Update with local details»
Name:	«name»
Address:	«address»
Telephone:	«telephone»
Research Nurse:	«Update with local details»
Name:	«name»
Telephone:	«telephone»
Complaints/concerns:	«Update with details for local complaints department and/or Patient Advice and Liaison Service»

Local Trust Headed Paper

Name: «name»
Address: «address»
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Chief Investigator:
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Northern Ireland Clinical Trials Unit (COMBAT Co-ordinating Centre):
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Transparency Statement

Queen's University Belfast, is the sponsor for the COMBAT study. The study sponsor is the organisation responsible for ensuring that the study is carried out to a high standard to safeguard patient rights and safety, and the quality of the research data.

How will we use your information?

We will need to use information from you and from your medical records for this research project.
This information will include your date of birth (DOB), sex at birth, sexual orientation, ethnicity, employment status, postcode, initials. We need this information because we want to ensure that people from all backgrounds are invited and have an opportunity to take part in COMBAT, if they wish.

We will also need to have your name and contact details to be able to contact you if you are selected to take part in the individual interviews, or if you express an interest in receiving a summary of the research findings.
If you are interested in taking part in the interviews and if you are selected to take part, you will be reimbursed for your participation and, if you choose cash payment, you will be asked to provide your bank details so that we can transfer the money directly to your account.

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 your contact details. Your data will have a code number instead.

International Transfers?
Your data will not be shared outside the UK

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.

We will keep your study data for a maximum of 5 years after the study has finished. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the COMBAT study at any time, without giving a reason, but we will keep information about you that we already have.
- If you decide to stop taking part in the study, we would like to continue collecting information about your health from your hospital or optometrist. If you tell us that you do not want this to happen, tell us and we will stop.

- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can find out more about how we use your information at

- http://www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipants.html
- https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/
- by asking one of the research team
- by sending an email to the COMBAT study team: combat@nictu.hscni.net
- by ringing us on (028) 961 51447
- by contacting the Queen's University Belfast Data Protection Officer - Information Compliance Manager (info.compliance@qub.ac.uk, telephone 028 90972576)