

<To be printed on Trust headed paper>

PATIENT INFORMATION SHEET

HOPON: Hyperbaric Oxygen to Prevent Osteoradionecrosis

You have been invited to take part in a research study. Before you decide it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and talk to others if you wish.

- Part One tells you the purpose of the study and what will happen to you if you take part.
- Part Two gives you more detailed information about the conduct of the study.

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.

Part 1

What is the purpose of the trial?

This study has been designed to find out whether the use of oxygen treatment may help your jaw heal after minor surgery. Healing problems can occur more often after radiotherapy.

We will take precautions to reduce the effects of surgery, but even so there is a small risk of healing difficulties. Having the extra oxygen treatment might prevent this although at the moment nobody knows this for certain.

This trial is to find whether there is any difference between two different types of treatment. If you agree to take part, you will be randomly allocated to one of two groups:

- 1) Surgery with antiseptic mouthwash and antibiotics.
- 2) Surgery with antiseptic mouthwash and antibiotics, also with oxygen treatment.

This means that half of all patients will be given oxygen treatment. Therefore whether you are allocated to be treated with oxygen will be decided by chance. Whichever group you are allocated you will be monitored closely.

Why have I been chosen?

You have previously received radiotherapy and now require minor jaw surgery. This may be to treat a dental problem, to place implants or simply the removal of teeth. After this surgery, difficulties with healing can occur and doctors use the term “osteoradionecrosis” of the jaw in these cases.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do you will be asked to sign a consent form. You are free to withdraw at any time and without giving a reason. A decision

to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Attendances, travelling additional costs

Involvement in the HOPON trial will require appointments at three and six months after jaw surgery. For those patients receiving oxygen treatment, daily visits to the oxygen treatment centre will be arranged. It may be possible for the health service to help with transport if needed, but these arrangements will vary in different trial centres. Please discuss transport arrangements if you feel this may be a problem.

What will happen to me during the trial?

For the patients receiving the oxygen treatment, they will receive it at a dedicated clinic. The oxygen treatment lasts about one and a half hours per day and is given as an outpatient, or in other words, you will be free to go home after this. The oxygen treatment consists of 20 treatments prior to surgery and 10 afterwards.

For the patients treated without oxygen, the surgery is carried out after giving antibiotics in the usual way.

For either group, whether surgery is done under local or general anaesthetic will be decided on by your surgeon or dentist in the usual way.

After you have been treated you will be required to attend hospital for a follow-up visit at 3 and 6 months. During these visits you will have an examination. Jaw x-rays and clinical photographs will also be taken.

One aspect of this study involves assessing how any treatment you receive affects the quality of your life and post-operative recovery. Our research nurses will ask you to fill in a questionnaire that asks these questions. The questionnaire will be completed when you consent to enter the study and attend for your treatment or follow-up appointments. It is very important for you to answer all the questions in the questionnaires for us to accurately assess the impact of the disease and treatment upon you.

Blood samples

Radiotherapy may lead to damage to tissues in and around the jaws. In order to further understand these changes we wish to collect and store a blood sample at the time of your minor surgery. These would be stored and used for scientific research but would not help with your care.

What are the alternatives for treatment?

If you decide not to participate in the study, then your doctor will discuss other options with you.

Are there any side-effects associated with these treatments?

Hyperbaric Oxygen Treatment:

Oxygen treatment in a high-pressure chamber has a proven safety record and many patients are routinely treated in this way. There are some medical conditions that prevent us recommending oxygen treatment therefore we will ask you particularly about some lung and ear disorders which may be relevant.

People having repeated treatments with high-pressure oxygen therapy sometimes notice a feeling of tiredness. This effect is apparent later in the day after a treatment in the morning and disappears by the following day. It is rarely, if ever, enough to interfere with normal daily activities. Some people notice temporary changes in their vision over the course of many treatments. This may cause a mild degree of short-sightedness, which may improve or worsen vision, depending on any pre-existing short- or long-sightedness. If this does occur, you can expect it to have returned fully to normal within six weeks of finishing treatment. Tiredness and temporary mild visual changes are common but will always resolve after these oxygen treatments.

The changes in pressure can cause damage to the middle ear or sinus if the pressures in them are not equalised. This may cause problems such as pain and/or a ruptured eardrum but is not common, occurring around one in fifty patients (2%). This can be prevented easily by notifying the attendant that you have a problem and the compression or decompression can be stopped immediately. These problems can often be anticipated and simple procedures may be used, such as drainage tubes in the ears, to prevent them if necessary.

The high-pressure chamber is a relatively confined space and it occasionally induces feelings of claustrophobia. About one person in fifty may be affected (2%). If you are, please remember that you are in control at all times and that you can leave the chamber at any time.

A very rare side effect of breathing oxygen at the pressure used is having a fit (seizure) and this occurs less than one in ten thousand patients (0.01%). This is short-lived and easily dealt with and there are no lasting effects. You may not be eligible to take part if you have had any seizures in the past, as this may predispose you to having an oxygen seizure. If there are abnormalities in the lung, or the person holds her breath, it is possible for gas bubbles to enter the blood and to cause problems. These complications are extremely unlikely with the slow pressure changes used in this study and can be totally avoided by carefully screening patients for lung problems, and by breathing normally at all times.

We have considered the theoretical possibility that high-pressure oxygen therapy might stimulate dormant cancer cells but there is no evidence that it does so. This therapy is commonly used in patients with a past history of other cancers.

Antibiotic Treatment:

Antibiotics of all types occasionally cause allergy or upset stomach. The antibiotics used in this study are in routine use.

What are the possible benefits of taking part?

We hope that the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to improve the future treatment of patients who have had radiotherapy to their jaws.

What are the possible disadvantages and risks of taking part?

As part of the study you will undergo at least two jaw x-rays. The dose of radiation you will receive could be equivalent to several years of natural background radiation. The National Radiological Protection Board described a few years natural background radiation as 'Low Risk'. However, you would receive the same dose from the x-rays in this trial as those

required by routine care in the NHS (UK) so you are not exposed to very much additional radiation by taking part in this trial.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in this study be kept confidential?

Yes. All information which is collected about you during the course of this research will be kept strictly confidential. With your permission we will inform your GP of your participation in the study. Other than this, any information about you that leaves the hospital will have your name and address removed so you cannot be identified from it.

Contact for Further Information

Should you have any further queries regarding this study or about any of the treatments described above:

Please feel free to ask your doctors any questions about the study or about any of the treatments described above.

Please contact _____
Name and Title

On _____

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 the additional information in Part 2 before making any decision.

Part 2

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she 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.

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

If you do not wish to continue attending hospital, we would be grateful if you would allow us keep in touch with your General Practitioner and Dentist to let us know your progress. If you withdraw, information collected may still be used if you allow. Any stored blood samples that can still be identified as yours will be destroyed if you wish.

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 questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

If you are harmed by taking part in this research project, 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 against the NHS trust where you are being treated but you may have to pay for your legal costs. The normal National Health Service complaints mechanisms should be available to you (if appropriate).

In the event of defective product then you may have grounds for a legal action for compensation against the manufacturer, but you may have to pay for your legal costs.

Will my taking part in this study be kept confidential?

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from Cancer Research UK or their collaborators who also involved in organising this research project. They may also be looked at by representatives of regulatory authorities and by authorised people from the Trust or other NHS bodies to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

Data collected during the study may be transferred for the purpose of analysis/registration within or outside the European Union. Some countries outside Europe may not have laws which protect your privacy to the same extent as the Data Protection Act in the UK or European Law. We will take all reasonable steps to protect your privacy.

Involvement of the general practitioner/ family doctor (GP)

With your consent, your GP will be informed of your involvement in the trial. Any other medical practitioners who treat you, e.g. should you be admitted to hospital for any reason, will also be informed.

What will happen to any samples I give?

With your permission, we would like to transfer a blood sample we take from you to the University of Liverpool and store them there. The researchers at the University of Liverpool

work closely with other scientists and, with your permission, your samples may be transferred to these research collaborators for use in future scientific studies. These samples will be used only for investigating the effect of your genetic (DNA) information on the severity of radiation damage and will not be used for any commercial purposes.

The samples will be kept in a secure place until we need them; nobody outside of the study will have access to **any** confidential information that you give to us. Confidential details (such as your name, address and GP details) will be kept locally and not made available to collaborators.

Your sample will be coded and the researchers carrying out tests on the samples will not be given information they do not need to carry out the tests and analyse the results. Coded is not the same as anonymous. It will be possible to use the codes to identify that a result is from your sample. However, we do not plan to do this unless there is a good research reason to do so. We will maintain this information so that we can properly manage the samples donated. For instance, sometimes we may need to update our record of your clinical details to help us interpret the results of tests.

Will any genetic tests be done?

There are some known genes that alter the body's response to radiotherapy and we may try to carry out research into these genes on your samples.

What will happen to the results of the research study?

It is intended that once the study is complete a report will be written and the results will be published to make them available to the public and medical community. You will not be named or identified in any publication.

Who is organising and funding this research?

This research project is funded by Cancer Research UK; they are supporting this study by providing funding for staff to co-ordinate this trial. It is being sponsored by the University Hospital Aintree NHS Foundation Trust and the University of Liverpool.

Your doctor will not receive any payment for including you in this study.

Who has reviewed the study?

The study has been reviewed for scientific content by members of the Cancer Research UK peer review committee and a Multi-Centre Research Ethics Committee has reviewed the study for ethical considerations. The trial has the support of the National Cancer Research Institute.

Thank you for taking the time to read and consider this information sheet. Should you decide to take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.