

INSERT LOCAL CONTACT DETAILS

headandneck 5000

INFORMATION LEAFLET

**United Kingdom National
Institute of Health
Research Study**

Summary of the study

You have been given this leaflet because you have been diagnosed with a head and neck cancer. The doctors and other health professionals who care for you would like to invite you to join a national study in which they are taking part. Cancers affecting the head and neck are not common, but about 7500 people are diagnosed every year in the United Kingdom. Until now research into these cancers has been limited. This study aims to recruit 5000 people with head and neck cancer. The study will be running in a number of head and neck centres around the UK. Your local Head and Neck Team have chosen to be part of this study. There are very strict rules about collecting medical research information under the 1998 Data Protection Act. We must follow this act and keep your information safe. Your data will be given a code and only Professor Ness and the research team will be able to link your code with you. By analysing this information, we hope to be able to help other people with head and neck cancer in the future.

Who is organising the project?

The project has been funded by the UK National Institute for Health Research. Researchers from Bristol University are leading the project and working with your local Head and Neck Team.

What is the purpose of the study?

The aim of the research is to look at care for people with head and neck cancer. This will be the largest study to examine the factors that affect outcome for people with head and neck cancer. This study will help us understand more about head and neck cancer and how we can improve care for people diagnosed with one of these cancers.

Why have I been chosen?

We are asking all people recently diagnosed with head and neck cancer to take part in the study. Not everyone will want to take part but the more people that join the study, the more meaningful the results will be.

Do I have to take part?

No. Some people will feel that they do not want to take part. Your care will be exactly the same whether you take part or not.

Are there any disadvantages in taking part?

The study will take up some of your time and we will collect 2 additional blood samples (usually at the same time as blood is collected as part of your treatment) and 1 additional saliva sample. Your medical care will continue exactly the same whether you take part or not.

What do I have to do to take part?

Taking part in the head and neck 5000 study involves completing questionnaires at the time you are diagnosed, and giving samples of blood, saliva and tissue. We will ask you to complete similar questionnaires four months later and again one year after your treatment. We would

also like your permission to allow us to link the information you give us to your records already held on existing databases (this makes the information more meaningful). The NHS Information Centre and the Medical Research Information Service (MRIS) will assist us with this data processing.

How do I join the study?

If you wish to take part you will be given further information by your local Head and Neck Team who will explain the process in detail and ask you to complete a consent form.

Will my privacy be protected?

When you fill out a questionnaire and consent to donating samples of blood, saliva or tissue, your privacy will be protected. All information and biological samples will be stored securely and confidentially.

What will the researchers do with my blood and tissue samples?

Providing a sample of your blood, saliva and tissue together with your questionnaire answers will allow the researchers to look at biological, medical and lifestyle variables and understand their influence on outcome in head and neck cancer. We may share these samples and information with other scientists who are doing ethically approved research, without passing on your name or other identifying details.

Can I withdraw from the study once it has started?

You may withdraw from the study at any time. If you have agreed to participate and have completed the questionnaire or provided samples you can still change your mind later. This will not affect your treatment, you just need to let us know. We can remove from the study any information or samples that you have provided and if you prefer we will not contact you again.

Who has reviewed the study?

This study has been reviewed by scientists and the study team has worked closely with people with head and neck cancer. A National Health Services Research Ethics Committee—SW5 (Frenchay) REC has approved the study. This is an independent panel that includes scientists, clinicians, patients and carers. The committee is satisfied that your rights are being respected and you have been given enough appropriate information to make an informed decision to participate or not.

Will I find out the results of the research?

It may be some years before the results of the study are available. Your care will continue as normal during the study. Once the study is completed the results of the study will be made available to you if you wish. The study has an informative website which may be useful if you have any questions or need more information. www.headandneck5000.org.uk.

Contact details:

If you have any questions about this study please feel free to contact your local team or the lead researcher for the study, who will be able to answer your queries or direct your questions to other members of the team.

Lead Researcher for study:

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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 to NHS Complaints Procedure <<*Local contact details to be inserted*>>.

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