TO GO ON HOSPITAL HEADED PAPER

The role of neck gland removal in the treatment of patients with small mouth cancers (tumour stage T1 and T2) where there is no obvious evidence of secondaries in the neck glands.

Sponsor: Queen Mary College University of London
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Patient Information Sheet, Version 11

Simplified Title: The role of selective neck dissection in early oral cancer treatment

Protocol Number: **SEND-001**

Doctor in Charge of Study: **Insert name of Principal Investigator**

Study Location(s): **Insert name of institution**

Invitation Paragraph

You are invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read this carefully. Our staff will help you and give you more information if you need it. You can also discuss it with others if you wish. Take time to read it and decide what you would like to do.

Purpose of study:

This study will compare 2 everyday surgical treatments for early mouth cancer. These treatments do not use any new or untried methods. Both of these treatments have a high chance of curing mouth cancer.

Mouth cancer, like all cancers, can spread. In mouth cancer this is usually to the lymph glands in the neck. These small cancer cells are called secondaries. They are usually found by looking or feeling or by using special scans. Research shows that 3 out of 10 patients with early mouth cancer have these small hidden secondaries in the neck glands that can't be seen, felt or even shown on special scans.

If we find secondaries in the neck we remove some of the lymph glands at that side of the neck. This is to remove these 'secondaries' and to help prevent the cancer from spreading. This is called 'selective neck dissection'.

We cannot tell which of our patients has these hidden secondaries, so this has led to uncertainty over whether we should remove the neck glands on all patients at the same time as removing their mouth cancer. There is currently no universally accepted evidence to show whether this is best for the patients or whether it is just as good to operate at a later date if and when secondaries develop.
We want to know

- If it is better to remove the glands at the same time the mouth cancer is removed, even if it does not seem that there are any hidden secondaries (selective neck dissection)

or

- Should we wait until we know that there are definitely secondaries and then remove them.

Why have I been chosen?

You have been chosen to take part in this research because**:**

There is no evidence that your cancer has spread to your lymph glands. However, this means that we cannot tell which is the best treatment. We are doing a study with 652 patients with the same condition as you. We are doing it in hospitals all over the UK and your surgeon thinks you are very suitable to take part.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. You would be free to withdraw at any time and without giving a reason. A decision to withdraw will not affect the standard of care you receive.

If you do not decide to take part in this trial, your surgeon will treat you as he/she normally would, probably by using one of the 2 procedures in this research study.

What will happen to me if I take part?

All the preparation and planning of your treatment will follow the normal standard procedures.

Surgery

All patients will have surgery to remove the primary cancer in their mouth completely. Half the patients will also have a selective neck dissection (surgery to remove the neck glands) at the same time. You will have an equal chance of having either treatment. It is important that neither you nor your doctor should choose which of the 2 treatment options you receive. The choice of which treatment you will receive will be made by the study's computer on a random basis. This is the only change to standard treatment practice and is done to ensure there is no bias and that the results of this research are scientifically sound and accepted by all surgeons and patients worldwide.

Tissue samples

We will ask your permission to collect 4 teaspoons (20 ml) of your blood at the time of surgery for future research. We will also ask you to allow us to store some of the removed cancer at the Human Tissue Resource Centre (HTRC) at St. Bartholomew's Hospital, London so that we can conduct research on this material in the future as new investigations or treatments become available. A small piece of normal tissue (about the size of a match head) will be removed from the edge of the tumour. This may be used in future research to compare with tumour cells. A saliva sample will also be collected.

You may, if you wish, donate blood, tissue and saliva samples even if you do decide not to take part in SEND.

Questionnaires

You will be asked to complete some questionnaires assessing your quality of life and emotional and psychological well-being after signing the consent form and 6, 12 and 24 months after your surgery. You will also be asked to complete a short questionnaire every 2 months following your surgery. This will ask you about visits you have made to hospitals or your GP. It will also ask you about any medicines that you have been prescribed. These questionnaires should take less than half an hour to complete. The questionnaires are for research purposes only, so you will not receive the results.

Follow-up visits

All mouth cancer patients are asked to attend clinics regularly for 5 years after their operation. The frequency of your visits will not change because you are participating in this study. You will be asked to attend the clinic once a month for the first year, once every two months for the second, and then once every three or four months for the remaining years. At some of these clinics a researcher will ask you questions about your health, symptoms, and level of physical and social functioning. Your surgeon may ask you to attend occasional clinics during the 6^{th}, 7^{th} and 8^{th} years following your treatment.

Further treatment

If you do not have a neck dissection at the same time as your mouth cancer is removed you may have this operation later, if you develop secondaries in your neck glands.

What is the procedure that is being tested?

We are comparing the two most commonly used surgical treatments for small mouth cancers. One treatment involves removing only the primary mouth tumour. The other involves removing the primary mouth tumour and carrying out a selective neck dissection at the same time.

We want to see:

- Which one may be better at preventing the cancer returning
- Which one might help people to live longer
- Which one helps you to live a more comfortable life

Is there any alternative to these treatments?

For patients with small mouth cancers such as yours, surgery is the usual treatment. Anti-cancer drugs (chemotherapy) are not, on their own, prescribed for mouth cancer but they may be used before or after surgery. Radiotherapy (similar to X-rays, but with more side effects) may also be used either on its own or before or after surgery.

What will happen to any samples I give?

The tumour and some of the tissue around it will be removed from your body. It will be examined in the pathology laboratory, following standard practice, to ensure that the cancer is eliminated. With your consent we would also like to take small parts of this tissue for special research analysis.

If you do consent to the use of your tissue and blood for laboratory studies we would also seek your permission to store the samples and use them for future research. All new research work will be subject to ethical approval. You will not be required to undertake any additional tests or make any extra visits to hospital.

The part of your sample, which is used to confirm that your cancer has been removed, will be stored in accordance with national guidelines and forms part of your medical record. The part of the sample taken for research will be stored securely in accordance with Medical Research Council guidelines (currently for ten years after the research has been completed). Any results from tests carried out on your sample are likely to be published in the medical literature, but individual patients will not be identified in these publications.

All your samples will be stored with a code number that does not contain any details about you although it will be possible to link the specimen with your study data so that researchers can, if necessary, compare the results of their analyses with the clinical results of the SEND trial.

Future research may include genetic analyses, which could help us understand how these tumours develop and spread. There is a need to learn about the genetic basis of these tumours, which might help us improve the diagnosis and treatment of mouth cancer in the future. The results may not benefit you personally, but should help future generations.

No results from these blood and tissue tests will be available to you, but you are free to discuss any aspect of this with your surgeon.

Will I have to alter my lifestyle?

There is nothing specific that you have to do and participating in the study will not place any restrictions on your lifestyle. For example, you will be able to drive, drink,

play sport as normal and take your regular medication. You should follow your surgeon's advice about lifestyle choices whether or not you decide to participate in this study

What are the side effects of any treatment received when taking part?

During Surgery

The side effects and risks for either treatment are those of any surgery including blood loss or reaction to medication. You will receive the normal full explanation that is given to all patients prior to this surgery before signing the consent form for surgery. If you are also having neck dissection you will undergo a longer operation and the surgical incision will be on your neck.

Whichever procedure is selected for you, your surgeon may decide that your mouth needs reconstruction after he/she has removed the mouth cancer. He/she may take tissues and grafts from around your head and neck or from your chest, arm or leg to reconstruct your mouth. This is normal practice and is used for all patients whether they are in the study or not.

After surgery

If you have only the mouth cancer removed you will need to stay in hospital for a few days after your operation. If you have a neck dissection you will be in hospital for several more days.

Any wound takes time to heal after surgery, and the time needed to recover is different for each person. You may be uncomfortable for the first few days but medicines can usually control the pain. Before surgery, you should discuss the plan for pain relief with your doctor or nurse. After surgery, your doctor can adjust the plan if you need more pain relief.

It is common to feel tired or weak for a while. Also, surgery may cause tissues in your face to swell but this swelling usually goes away within a few weeks. Your treatment may affect your speech, chewing and/or swallowing.

If you are one of those patients having neck surgery to remove some lymph nodes, you will have more side effects. All of these patients will have neck scars. All of these patients are likely to experience areas of numbness and weakness of the neck. About a quarter of neck dissection patients will have stiffness or weakness of the shoulder on the side of the surgery.

What are the possible disadvantages and risks of taking part?

There are no specific risks in taking part in the study as both treatment approaches are standard treatments, although you may experience some of the side effects listed above.

If you have private medical insurance you should check with the company before

agreeing to take part in the trial, to ensure that your insurance is not affected in any way.

What are the possible benefits of taking part?

The results of this research will benefit all patients with mouth cancer in the future as it answers a specific area of uncertainty in our treatment planning. You will be helping determine best treatment practice for future patients. You may benefit if you have had the treatment that the results of this study prove to be the best.

What if new information becomes available?

Sometimes during the course of a research project, new information about the treatment that is being studied becomes available. If this happens, your research doctor will tell you about it and discuss with you whether you would like to continue in the study. If you decide to withdraw, your surgeon will make arrangements for your care to continue.

What happens when the research study stops?

Once the study is completed you will continue to be seen by your surgeon as part of your routine care.

What happens if there is a problem?

Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action. For further information or for initial concerns or disagreements please contact **(local details)**. You can also visit PALS by asking at any hospital reception.

Will my taking part in this study be kept confidential?

If you consent to take part in this study, all information collected about you during the course of the study will be kept strictly confidential. Details about you, the treatment you receive and your subsequent progress will be recorded in your medical notes and will be passed on to the Facial Surgery Research Foundation Trials Centre, which is registered under the Data Protection Act. These details will include your name, date of birth and hospital number. The information collected will be primarily to do with the treatment you receive, the side effects that you may or may not experience and your long-term state of health. In order to check that the information sent to them is accurate and that the study is being carried out properly, staff from the trial centre may wish to see your medical records. We will ask your permission to inform your GP of your participation in the study and may contact your GP for follow up information if you are unable to attend hospital appointments. We will also request

your permission to register your details with the Office for National Statistics (ONS) so that we may follow your health status.

What will happen to the results of the research study?

The results from the study will be published in medical and scientific journals. You will not be identified in any report or publication arising from this study.

Who is organising and funding the research?

Cancer Research UK is funding the study. Neither the surgeon conducting this research nor you own surgeon will receive any special or additional payment because you have agreed to participate in the study.

Who has reviewed the study?

Many of the UK surgeons specialising in mouth cancer, the National Cancer Research Institute (NCRI) Head and Neck Cancer Studies Group, Cancer Research UK and the International Academy of Oral Oncology have reviewed and approved this study.

Contact for Further Information

If you have any concerns or questions about this study please contact one of the medical team caring for you.

Consultant

Phone No……

Research Nurse or other trial support staff

Phone No……

CancerHelp UK provides general information for patients about cancer and its treatment on their website, www.cancerhelp.org.uk.

Cancer Research UK has cancer information nurses who provide a confidential service, Tel: 020 7061 8355 or 0808 800 4040, email: cancer.info@cancer.org.uk.

MacMillan Cancer Support provides support and counselling to help people living with cancer, Tel: 0808 808 0000, www.macmillan.org.uk.