

Voice changes after thyroid surgery

- impact of early voice therapy

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Patient information sheet

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We would like to invite you to take part in a research study organized by the Endocrine Surgery Unit and the Voice Clinic. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully.

You have been seen by one of the surgeons in the clinic today, who has explained the surgical procedure and may have mentioned the study that we are running. We have set up a study, where patients who undergo thyroid surgery are assessed for the existence of subtle voice changes that might be present before the operation or might develop after the operation. The aim of this study is to determine whether such voice changes can be reduced in frequency/severity by using regularly a set of simple voice exercises described on a DVD and written information sheet.

What happens if I take part?

This study will not interfere with your normal treatment and follow up after you thyroid operation.

The current care of patients undergoing thyroid surgery include

- an examination of the voice box using a fine flexible camera (nasal laryngoscopy). This is performed before and after the operation in patients with voice problems
- assessment and treatment in the Voice Clinic if patients develop voice symptoms persisting for more than 3 months after their operation.

As part of this study we aim to provide further assessments and support:

- you will be asked complete a questionnaire investigating the amount of voice use in your day-to-day life and any possible voice changes that you might be aware of. This questionnaire will be used before the operation and at 1 week and 6 weeks after the operation.

- you will have a nasal laryngoscopy to check the function of the voice box before and after the operation
- you will be offered generic advice on “voice hygiene”
- you will be randomized (i.e. selected by chance by drawing a random envelope containing a code number) to either i. have nothing else to do or ii. receive written instructions and a DVD with a video demonstrating voice exercises that should be used daily as soon as possible after the operation and for some 2-6 weeks. It will be entirely up to you if you want to follow these exercises at all, how many times daily and for how long. We only want to learn from you whether or not you used these exercises. There is a 50-50 chance for each patient to be drawn in one of these two groups.

All patients who develop voice problems will be assessed at 3 months, 6 months or until their voice recovers.

What happens if I do not take part? Your care will not be affected if you refuse to take part. Your operation will follow as scheduled and you will continue to be reviewed in the clinic in the same manner as patients have been looked after so far.

Do I have to take part? Participation in the trial is entirely voluntary. As a study participant you have the right to withdraw at any time, without giving any reason. This participation or withdrawal will not affect your future medical care or relationship with the doctors and nurses.

What are the possible risks of taking part? There is no risk associated with this trial.

Are there any possible benefits? We hope that this study will clarify the incidence (frequency) of voice symptoms after thyroid surgery, will help understand the time-scale needed for such symptoms to resolve and will investigate whether the recovery is facilitated by early initiation of voice therapy exercises.

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. Any concerns can be discussed with the *Patient Advice and Liaison Service* (PALS).

Will my taking part in the study be kept confidential? We will follow ethical and legal practice and all information about you will be handled in confidence. Instead of printing your name/address/date of birth on the paper questionnaires we will use the “code” drawn at random at the beginning of the study based on which you are allocated to one of the two groups in the study.

What will happen to the results of the research study? It is our intention to present these data to learned societies and to publish it in a peer-reviewed medical journal. **No patient** will be identified in any report/publication.

Who is organising and funding the research? This research project is organized and run within the Oxford Radcliffe Trust.

Who has reviewed the study? All research in the NHS is looked at by independent group of people, called a *Research Ethics Committee* to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favorable opinion by Oxford Local Research Ethics Committee B in October 2009.

Will my records be used for any other purpose? The records that we will keep for the study may be inspected by the Research Department of the Trust. Personal details, however, will never be given to any company or authority.

What do I do now? We advise you to consider the information provided and discuss the study with your family or GP. Do not hesitate to ask further questions. If you have any questions about this study, please contact Mr Radu Mihai (tel 01865 221189, email Radu.Mihai@orh.nhs.uk).

If you decide to join the study, on the day of the operation we will ask you to sign an additional consent form that confirms that you are willing to participate in the study. You will then be allocated randomly (i.e. by chance) either to the group that receives the DVD with voice exercises or to the group that receives only generic advice.

Thank you very much for considering this study !