

PARTICIPANT INFORMATION SHEET

The TYPHOON Study

TONSILLECTOMY POSTOPERATIVE HAEMORRHAGE OUTCOMES AND OBSERVATIONS NATIONAL COHORT STUDY

1.1 Introduction

We are a team of surgeons involved in the care of patients having a tonsillectomy. We are inviting you to participate in research looking at complications following tonsillectomy, particularly bleeding.

1.2 What is the purpose of this research?

A recent large trial in the UK (<https://research.ncl.ac.uk/nattina/>) demonstrated that tonsillectomy is an effective treatment for patients with recurrent sore throats. Bleeding after the surgery is one of the most important risks of tonsillectomy surgery, and can range from small streaks of blood in the saliva to more severe bleeding requiring further surgery. Over the last 10 years, there has been a significant increase in the number of patients returning to hospital with either bleeding or severe pain following surgery, the reasons for which are currently unclear.

The aim of this research is to investigate the factors associated with bleeding and other complications in the first 28 days after a tonsillectomy. We hope the results of the study will help improve the standard of care we offer to patients undergoing tonsillectomy.

1.3 How are we selecting patients?

You have been provided this leaflet as you are having an operation to remove your tonsils.

1.4 What would taking part involve?

You will meet one of the researchers on the day of your surgery and encouraged to ask any questions about the study. You will be asked to sign a consent form should you agree to participate. The investigating team will then ask you to fill out a questionnaire called the Tonsillectomy Outcome Inventory-14 (TOI-14), which is often used to assess how tonsillitis has affected quality of life. We anticipate this will take 10 minutes. We will telephone you at 28 days after your operation and ask if you have had any bleeding from your mouth, and if you sought medical help. We will also ask you about your use of painkillers.

1.5 Do I have to take part?

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate your care will continue as normal.

1.6 Will there be any future research coming from this study?

1.11 Your consent in participating for this study also involves the opportunity to participate in future studies using the data that we have collected from the study. Please let the research team know if you would not like to do so.

1.7 What are the possible disadvantages and risks from taking part?

The main disadvantage will be taking up the time in participating in the study.

1.8 What are the possible benefits from taking part?

We do not anticipate any immediate benefits to you from this research but we hope this may help patients undergoing tonsillectomy in the future. Any results obtained from the research may or may not be used to develop a new drug, treatment or investigation. However, your involvement in the study will not financially benefit you from any new drug, treatment or investigation.

1.9 What will happen with the results of this study?

Results from the study will be submitted for consideration of publication in the medical literature and shared at academic conferences for professionals involved in the care of tonsillectomy patients. Confidential information will not be shared.

1.10 What right to I have over my data?

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at <https://www.hra.nhs.uk/information-about-patients>. Personal data will be collected and stored in compliance with the Data Protection Act 2018 and the General Data Protection Regulation (GDPR).

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

You can choose to stop participating in the research at any time without giving a reason. Your treatment will not be affected in any way. Any data collected up to withdrawal from the study may still be used.

1.13

1.12 Who is sponsoring the project?

NHS (National Health Service) Greater Glasgow and Clyde is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS Greater Glasgow and Clyde will keep identifiable information about you for 5 years after the study has finished.

1.13 What if something goes wrong?

If you have any concerns about any aspect of this study, you should ask to speak to your local TYPHOON study site contact (details below). If you would like to complain formally, you can do this by contacting the TYPHOON study team at typhoonstudy@entintegrate.co.uk.

We do not anticipate that anything will go wrong. If you are harmed due to someone's negligence, or your participation in the study you may have grounds for legal action for compensation against the sponsor (Greater Glasgow and Clyde Health Board), but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms are available if you wish to complain or have any concerns (Tel: 0141 201 4500, Email: complaints@ggc.scot.nhs.uk).

1.14 Who to contact if I have questions?

If you have any questions about this research, you can ask any member of your usual care team or the TYPHOON study team at typhoonstudy@entintegrate.co.uk. Additionally, contact information is provided below:

Local TYPHOON study site contact:

[Redacted]

Email:

[Redacted]

Alternatively, if you have concerns, you may wish to contact PALS (Patient Advice and Liaison Service) who provide independent advice and support to NHS patients and their relatives and carers at [REDACTED].

.