

You are being invited to take part in a research study to be carried out at Beaumont hospital operating room by Dr Michael Moore, Chandar Parkash Maheshwari and Dr Edel Duggan. Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'. You don't have to take part in this study. If you decide not to take part it won't affect your future medical care. You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you receive.

Why is this study being done?

All anaesthesia requires the safe provision of oxygen and anaesthesia gases. These are delivered through a tube called an endotracheal tube, which is placed by the anaesthetist in the patients wind pipe (trachea). This at times can be difficult to do. A fiberoptic camera can be used to place this tube when difficulty arises or is expected. All anaesthetists need to be trained to use fiberoptic camera. You may have a small device called infrared red intubation system (IRRIS) in the front of your neck before you are put to sleep for your operation. Our study is to see if the IRRIS device makes it easier for the anaesthetists to see the wind pipe.

Who is organising and funding this study?

The department of anaesthesia is organising the study and will be carried out in theatre by the anaesthetist. This research is not a prerequisite of academic qualification. There is no money involved in this work for any doctor, patient or the hospital.

Why am I being asked to take part?

You are being requested as you are scheduled for general anaesthesia in Beaumont hospital.

How will the study be carried out?

This study will be conducted in operating room of Beaumont hospital from 15th November, 2018 for 6 months. In this study we will not take any blood or tissue sample. During general anaesthesia, for delivery of oxygen and anaesthetic gases a small tube is passed in the wind pipe (Trachea). This tube will be passed with the help of fiberoptic camera. A small device is called IRRIS device as shown on page 5 may be placed on your neck to aid the passage of the fiberoptic camera. You will be

undergoing for general anaesthesia for the operation. When surgery is completed you will be woken up and returned to the recovery room until ready to go to the ward. After that you don't need to fill any questionnaire or revisit us again for this study.

What will happen to me if I agree to take part?

If you agree to become a part of this study an anaesthetist will visit and explain the process. You don't need to fill any questionnaire and even you don't need to give any blood sample or extra visit to hospital for this research purpose. Anaesthetist will review your chart not for research purpose but as per your preanaesthesia assessment. You will arrive in anaesthesia room where anaesthetist will insert a small tube (cannula) on the back of your hand and may put the IRRIS device on the neck. The anaesthetist will then give you general anaesthesia. The anaesthetist will monitor and take care till the operation is completed.

What are the benefits?

The benefits of taking part mean that anaesthetist will use the IRRIS device in patients during fiberoptic intubation. This may make fiberoptic intubation safer for the patients.

What are the risks?

There are no real risks to you. Trauma to the airway can occur as a result of the administration of general anaesthesia, this would be a risk with or without use of fiberoptic scope and IRRIS device.

Is the study confidential?

Yes, it is completely confidential. All data collected during the study will be stored in a paper folder in locked cabinet of anaesthesia department, beaumont hospital. No patient identifier will be present at any stage on the data collection sheet. The contents of this folder will be shredded after May 2019. We propose presentation of the data at national and international conferences and ultimate publication of the results in a high-quality peer-reviewed journal. The results of the study can be discussed with you at a later stage if you require them.

Data Protection "You have the right to withdraw consent to your personal data being used in this research project. You will be able to do this by contacting Principal Investigator at Tel No.01 8092773

1. We will be using your personal information in our research to see if the IRRIS device makes it easier for the anaesthetist to see the wind pipe.

2. Your data will be processed according to article 6(1)(e) for Public interest and article 9(2)(1) for scientific research purpose only.
3. The Principal Investigator will have access to your information
4. Data will be retained on a hospital computer until the results will be presented in national or international conferences and published in peer review Journals.
5. All the data will be anonymised and totally confidential
6. You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. For withdrawal you need to inform the principal investigator on the telephone number provided in the information leaflet.
7. You have a right to complain to the data protection commissioner if your data is used for purposes other than research.
8. You have a right to request access to your data and a copy of it, unless your request would make it impossible or very difficult to conduct the research.
9. You have a right to restrict or object to the processing of your data, unless your request would make it impossible or very difficult to conduct the research.
10. You have a right to have any inaccurate information about you corrected or deleted, unless your request would make it impossible or very difficult to conduct the research.
11. You have a right to have your personal data deleted, unless your request would make it impossible or very difficult to conduct the research. e.g. you wanted to delete your data at the end of a research project just before it is due to be published.
12. You have a right to data portability, meaning you have a right to move your data from one controller to another in a readable format.
13. You have right of automated decision making, including profiling? Profiling is any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to the person, in particular to analyse or predict aspects of their performance at work, health or behaviour.
14. You have a right to object to automated processing including profiling if you wish.
15. We are not intend to further process your personal data except this research project.

16. Your data may be transferred to a country outside of the EU or an international organisation for the purpose of publishing the study in a medical journal. Only anonymised data will be transferred and your personal data will not be identifiable.

Where can I get further information? If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future. If you need any further information now or at any time in the future, please contact:

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