



OSCAR STUDY INFORMATION ABOUT THE RESEARCH (Welfare Guardian/Nearest Relative)

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ISRCTN10416500

Hospital Trial ID Code:

Title of project: A study to investigate whether high frequency oscillatory ventilation or conventional positive pressure ventilation is of benefit to patients in the Intensive Care Unit.

Principal Local Investigator [Name and telephone number here]

PART ONE - INVITATION TO JOIN THE OSCAR STUDY

You will know from talking with the doctor that your relative has a serious breathing problem. This must be an extremely anxious time for you. We would however be grateful if you would take a little time to read this information. It asks you to think about allowing your relative to join a study which is taking place in many hospitals in the UK. Normally we ask patients themselves to consider taking part in research studies, but as your relative is on a breathing machine we can't discuss it with him or her.

What is the purpose of the study?

This study is comparing two ways of providing help with breathing for patients with serious breathing problems:

1. conventional ventilation (often called artificial ventilation or "breathing machine")
2. high frequency oscillatory ventilation.

Conventional ventilation

This sort of ventilation helps breathing by pushing a mixture of air and oxygen into the lungs every 2-4 seconds. We call this conventional ventilation because it is the most common method used.

Your relative is already receiving conventional ventilation. This form of care is standard treatment, and has been used for many years. However, using a conventional ventilator to deliver air and oxygen may itself sometimes cause some further damage to the air sacs (alveoli) in the lungs and delay recovery. This happens in about 1 in 12 patients who are ventilated.

High frequency oscillatory ventilation

Another way of ventilating patients is called 'high frequency oscillatory ventilation', sometimes abbreviated to HFOV. This involves giving very small breaths of air and oxygen very rapidly (up to 5 times per second far faster than conventional ventilators can provide breaths). As the breaths are very small they do not stretch the lungs very much and so might reduce the chances of causing further lung damage. However, the disadvantage with this type of ventilation is that the patient usually requires more sedatives.

This way of ventilating patients with severe breathing problems might be as effective, or better than conventional ventilation but currently there is not enough information to know which. Studies to date have not shown a clear answer. This is why we are undertaking the study.

What would being in the study involve?

Whilst in the Intensive Care Unit:

If you agree to your relative taking part, he or she will be assigned to receive one of the two forms of ventilation offered:

- Half the patients in the study will continue to be treated on conventional ventilation.
- The other half will be treated with high frequency oscillatory ventilation.

Neither you nor the doctor (nor anyone else) will know beforehand which of these two treatments your relative will get if you agree. This will be determined by the play of chance, rather like the toss of a coin. This element of chance is important so that the two methods can be tested fairly. When one of the two ways of ventilating your relative has been allocated, they will either remain on a conventional ventilator or be placed onto a high frequency oscillatory ventilator.

Information from your relative's medical record will be collected during their stay in the Intensive Care Unit. This information will be kept strictly confidential.

The study is only looking at the different forms of ventilation; other elements of your relatives care are not affected and will be decided in the usual way by the doctor caring for them.

After your relative has left the Intensive Care Unit:

As we are interested in the long term wellbeing of your relative, we will send him/her a questionnaire at six months after treatment in the Intensive Care Unit. The questionnaire will ask how your relative's breathing is affecting day-to-day activities, and about their general health. We will also send the same questionnaire to him/her after 12 months. We may send up to three more questionnaires, again spaced six month apart.

There are *no* further tests or hospital visits involved in taking part in the study.

Over 1,000 patients like your relative from hospitals across the UK will take part in this study. They are all helping to help find out which procedure is the safer, and more effective, at aiding breathing both in the short and long term.

Why am I being asked to consider the study?

Normally we ask patients themselves if they would consider taking part in research studies, but as your relative is on a breathing machine we can't discuss it with him or her. We are, therefore, approaching you (someone who has patient's welfare and best interests in mind), whether, in your opinion, your relative would have wished to take part in this study if they were able to make the decision themselves.

- If you believe your relative *would* have wanted to take part in this study, we would like you to give your consent for him/her to take part.
- If you believe your relative would *not* have wanted to take part, we will not include him/her in the study.

Declining to join the study will not affect the standard of care your relative receives.

If you (or your relative when he/she regains capacity), change your mind, they can be withdrawn from the study at any time. This will not adversely affect he or she's care. The patients (and their doctors) who take part in this study are not paid to do so and participate freely.

Do I have to agree to my relative being involved?

It is up to you to think about your relative's wishes and decide.

We will describe the study and go through this information sheet with you and you will be given a copy read. If you agree, we will ask you to sign a consent form to show you have agreed, and provide you with a copy.

When your relative is well enough to make a judgment about being in the study we will ask them. If they decide not to continue in the study they can withdraw.

If, after reading Part One, the study sounds like something your relative might have agreed to, you may find it helpful to read the further information in Part Two before you make your decision.

PART TWO - ADDITIONAL INFORMATION FOR RELATIVES WHO WOULD LIKE TO KNOW MORE ABOUT THE OSCAR STUDY

Who is organising and funding the research?

The Intensive Care Society's Trials Group at the University of Oxford is organising this research and work with the consultants and nurses in hospitals around the UK.

The National Coordinating Centre for Health Technology Assessment (part of the Department of Health/UK Government) is funding the research.

Who has approved the study?

Any research involving a person who lacks capacity may only be lawfully carried out if an NHS Research Ethics Committee (REC), has given the research their favourable opinion. They look after your relative's rights, well being and dignity.

This study has been reviewed and given a favourable opinion by a REC. The REC reference number is given on the front page of this document.

This study was also reviewed by the National Coordinating Centre for Health Technology Assessment before it was awarded funding to ensure it met the necessary scientific standards.

Is there a contact point where I can seek independent advice about participating in the study?

Yes, the Trust's Research and Development (R&D) Office can be contacted. They will give you advice about who you can talk to for independent advice. Ask one of the doctors or nurses for the R&D telephone details.

If you would like more information about the study itself you can ask to speak to the research lead for the OSCAR study at this hospital. His/her contact details are on the front of this information.

More about conventional and high frequency oscillatory ventilation:

Conventional ventilation is usually undertaken with an artificial ventilator which fills the lungs with an air/oxygen mixture at regular intervals. Even though the breaths are small (about half a litre), patients who have lung conditions that cause stiff lungs may have a delayed recovery because the lungs expand unevenly and some areas get overstretched and damaged. We believe this happens in at least one in twelve patients.

If the breaths are made really small (a twentieth of a litre or less) it may be possible to reduce the damage caused by stretching. However, to move enough oxygen in and out of the lungs, the breaths have to be delivered very rapidly, at about 5 breaths per second. An analogy is often made with panting dogs, who breathe rapidly with small breaths. However, as very rapid breathing is not "natural" for humans, patients receiving high frequency oscillatory ventilation often require more sedation to allow them to tolerate the breathing machine, and so may be sleepier when you visit.

We would like to determine which technique for artificial ventilation is best, and so we are conducting a study where half of the patients receive conventional ventilation and half receive high frequency oscillatory ventilation. As well as looking at how long patients require treatment in the ICU, we will

follow patients with questionnaires for up to two and a half years to see if the type of ventilation used has any effect on longer-term health.

Are there any risks?

All forms of artificial ventilation are used to treat very severe lung problems and all carry risks. One possible risk with high frequency oscillatory ventilation is that air will not have time to leave the lungs and will be trapped. This risk is minimised by not including patients likely to suffer this problem in the study, and by carefully monitoring the pressures and gas volumes delivered by the ventilator.

What if something goes wrong?

Compensation for harm arising from an accidental injury and occurring as a consequence of your relative's participation in the study will be covered by the University of Oxford. If your relative is harmed and this is due to someone's negligence they may have grounds for legal action for compensation against the University of Oxford (in respect of any harm arising out of the participation in the study) or the NHS (in respect of any harm which has resulted from the clinical procedure being undertaken).

You mention sending a questionnaire to my relative later. What will the questionnaire contain?

The questionnaire is in two parts. One section is about your relative's breathing and asks how it affects day-to-day living. The second section is a more general assessment of your relative's well-being.

The questionnaire will be posted from the co-ordinating office at Oxford University to your relative's home address. Once completed, it can be returned in a freepost envelope (no stamp required), which is supplied.

The first questionnaire will be sent to your relative six months after treatment in the Intensive Care Unit. The second six months later (12 months after intensive care). We may send them a further three questionnaires. Each of these will be sent six months apart.

As people may move house, we also collect the names of two friends/relatives who can help us locate a patient who has moved.

What if my relative wishes to withdraw from the study once he/she returns home?

Once your relative goes home the only involvement in the study is completing the follow up questionnaires asking how his/her breathing is. If your relative does **not** wish to receive a questionnaire they can tell us by telephoning the study co-ordinating office (tel: 01865 857613). No further questionnaires will be sent to them.

Are my relatives details kept confidential?

The information collected about your relative during the study will be kept in a secure area of the hospital behind double locked doors. All computer systems are on secure networks and all information is treated as strictly confidential. Any published reports will not identify your relative or any other patients.

Parts of your relatives' medical records and the data collected for the study will be looked at by authorised persons from the sponsor of the research and/or the funding body carrying out monitoring or auditing. This is to ensure the study is being carried out correctly. Identifying details will be sent to the Office of National Statistics and the National Health Service Central Register to aid follow up. All those involved in the research and the organisations supporting research have a duty of confidentiality .

Communication with GP

We will send a letter to your relative's family doctor informing them that your relative was entered into the OSCAR study whilst in the Intensive Care Unit.

What if I (my relative) wish to complain?

If you have a concern about any aspect of this study, you should ask to speak to the Principal Local Investigator in the first instance. Their contact details are on the front page of this information sheet. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Where can I find the results of the study?

A detailed study report will appear on the National Coordinating Centre for Health Technology Assessment website (NCCHTA, part of the Department of Health) in 2013, and will be free to download. Printed copies will also be available. The study reports will also appear in the medical journals.

Thank you for taking the time to read this information.

If you believe your relative would have wanted to take part in this study, and you would like to give your consent, please let one of the Intensive Care Unit staff know.

Please remember we will ask you for the contact details of two friends of your relative to help us keep in contact should your relative move house.