The InSTAR study

**Does use of nebulised, localised steroids (budesonide) in Acute Respiratory Distress Syndrome (ARDS) patients in intensive care requiring mechanical ventilation reduce all-cause mortality at 28-days? A randomised trial.**

Participant information Sheet

**Nearest Relative/Welfare Attorney/Welfare Guardian**

We have spoken to you about this study because your relative has been placed on a ventilator due to them requiring more oxygen than can be delivered from a facemask. There are many causes of this, but all these causes can be classified as Acute Respiratory Distress Syndrome (ARDS). This study is looking to see if giving an inhaled drug can help improve survival in patients with ARDS.

* We want to invite people with ARDS who are currently on a ventilator in the intensive care unit to participate in a research study. The study aims to test whether using a medicine called budesonide for 5 days improves recovery
* Budesonide is a type of medication called a steroid, which is used to reduce inflammation/ swelling in areas such as the lungs. The study uses inhaled Budesonide that is breathed in through the ventilator.
* Doctors have a lot of experience of using inhaled Budesonide. The most common side effects are an irritated throat, hoarseness, cough, difficulty swallowing and a type of mouth infection. These happen mostly with long term use, this study will only use Budesonide short term.
* Half of the people in the study will receive inhaled Budesonide along with our normal standard care. The other half will receive standard of care as normal.
* All the data needed for the study will be collected from your relative’s ward’s medical record. This information will be stored securely on computers at the University of Aberdeen (called servers) and will be treated confidentially.
* If you have questions telephone [xxx], speak to your hospital team, or visit [URL].

**Further details**

## 1. Who can take part?

* Adults aged 18 or over with who are in intensive care and on a ventilator, a type of breathing machine.

**2. Do they have to take part?**

* No, joining the study is voluntary. If they are not in the study, he or she will receive our normal standard care. If at any point in the study you or a doctor decide you want to stop the involvement in the study, you are free to do so. It will not affect the care they are given.
* If you do not want more information to be collected about the patient, please tell the research team. Any anonymised information that has been collected up to that point will continue to be analysed.

**3. What is the purpose of the study?**

* Up to one in three patients with ARDS will not survive and we need to find potential drugs to improve this.
* This study will test whether using a medication called inhaled Budesonide for 5 days on people with ARDS on a ventilator in Intensive care will help them recover. Budesonide is a steroid. Steroids appear to be helpful for people on ventilators, but we don’t know for certain whether using them is more helpful than the care we normally give people. Every person will receive the same standard of care but, as part of the study, some people will receive Budesonide in addition to normal standard care.

## 4. What will happen to them in the study?

* A computer will allocate them at random (like rolling a dice) to one of the possible treatment options; either Budesonide in addition to normal standard of care or normal standard care without Budesonide. Neither you nor your doctors can choose which of these options they will receive.
* The Budesonide will be given through the ventilator so that he or she can breathe it in. Ventilators have a standard system for doing this, which we will use.
* We will collect data from their medical record about how he or she does.
* There are no additional visits. They will be in the study until 28 days after he or she was allocated a treatment by the computer.

## 5. What are the possible benefits of being in the study?

* Taking part in and completing the study may or may not help your relative or friend. The study results will help decide how future patients are treated. Budesonide is widely used and generally causes few if any problems for people taking it.

## 6. What are the possible risks of being in the study?

* Doctors have a lot of experience in using Budesonide.
* The most common side effects are throat irritation, hoarseness, cough, difficulty swallowing and a type of mouth infection. These are much more common in long-term use than with short-term use as in this study. Everyone looking after them will know what treatment they are getting and what side effects to look out for.

**7. Who is doing the study?**

* The study is led by Dr Callum Kaye, Anaesthesia and Critical Care Consultant, NHS Grampian. Researchers at the University of Aberdeen are working with him on the study.
* NHS Grampian and the University of Aberdeen are the organisations legally responsible for the study and has insurance in place in the unlikely event that a patient suffers any harm as a direct consequence of being in the study. NHS indemnity operates in respect of the clinical treatment that is provided.
* The study is paid for by [funder]. None of the clinical or research staff receive payment for asking people to take part.

**8. What information do you hold and how do you keep it private?**

* We use a special identification number and any information we collect will be stored using this number, rather than using any personal details. Data will be stored for 25 years.
* All the data we use in the study will come from the patient’s medical records. All information we collect during the course of the study will be kept private on computers at the University of Aberdeen. There are strict laws which safeguard the privacy of study participants at every stage, which we will follow. The only people allowed to look at the information will be the doctors and researchers running the study, and the regulatory authorities who check that the study is being carried out correctly.
* An anonymous version of the study data may be shared with other researchers to support future research.
* A privacy notice is on the study website [URL].

**9. What happens with the results of the study?**

* The anonymised results will be put onto our website, as well as published in a scientific article so that other researchers and doctors can use them in their work.

**10. What else can you tell me?**

The study has been reviewed by an NHS Research Ethics Committee, who have responsibility for checking proposals for medical research on patients. In addition, the study has also been reviewed and approved by the Medicines and Healthcare Products Regulatory Agency. The Research and Development Department of your local hospital has also reviewed and approved the study.

* The dosing of Budesonide is 1mg twice daily for up to 5 days. The twice daily doses will be given approximately 12 hours apart.
* If you believe that you or the patient have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of the study - the University of Aberdeen and NHS Grampian. Contact details for both research sponsors are available through the research team.
* As a patient of the NHS if the patient is harmed due to someone’s negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.
* If you have a concern about any aspect of this study you should ask to speak to the study doctors who will answer your questions (contact details are at the end of this information leaflet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints mechanisms (or Private Institution). Contact details can be obtained from your local hospital or from the InSTAR study office. In addition to this, you may contact the chairman of the InSTAR Trial Steering Committee (who is independent from the study) through the InSTAR study office.
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## 11. If I have any questions or problems, who can I call?

* If you have any concerns about the study please telephone [xxx] or speak to your hospital medical team. Further information about the study is also be available on the study website (URL to be confirmed).