Radar2

# Role of Active Deresuscitation After Resuscitation-2

## Information Sheet and Personal Consultee Declaration

**A research study to determine whether restriction of fluid intake and titrated use of diuretics to remove accumulated fluid is feasible, safe and of potential value in critical illness.**

We would like your relative/friend/partner to take part in a research study while they are a patient in this Intensive Care Unit. Unfortunately, they are not well enough to be able to decide for themselves whether or not they would like to participate. We would therefore ask you to read this Information Sheet carefully and give your opinion as to whether or not you think your relative/friend/partner would be willing to participate in this medical research. You may discuss this with others if you wish.

When your relative/friend/partner has regained consciousness and has the ability to understand the purpose of this study, we will explain the study to them and seek their permission to continue to participate in the research. Your relative/friend/partner's decision to continue or withdraw from the study will override the advice you have given.

If you have any further questions either now or at any time subsequently, please feel free to contact a member of the research team (details at the end of the Information Sheet).

**Please read the following information carefully. Thank you for your time in considering this request.**

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## Information Sheet

### What is the purpose of the study?

Most patients admitted to the Intensive Care Unit (ICU) receive a drip containing fluid into their veins, to try and help ensure flow of oxygen around the body. They also usually receive medications diluted in fluid, and fluid-containing tube feeds. When patients are very unwell in ICU, their kidneys are often unable to remove any excess fluid, and it often builds up in the body. Sometimes this can be obvious as swelling of arms, legs or even face.

Some studies have suggested that even though giving fluid to patients can be helpful, the prevention or treatment of any build-up of fluid may speed up recovery and reduce the risk of death. We do not yet know if this is the case.

The purpose of this study is to test whether a strategy which we have designed (involving giving less routine fluid and using diuretic drugs to make the kidneys remove more fluid) is effective in reducing the fluid build-up. If it reduces fluid build-up, we hope to undertake a larger study in the future to test whether it helps patients to recover from their critical illness and reduces the risk of death.

### Why has your relative/friend/partner been chosen?

Your relative/friend/partner is critically ill, needing help from a breathing machine (ventilator). We think that treating patients in this situation with a strategy of giving less 'routine' fluid, and then giving diuretic drugs, may improve their recovery and reduce the risk of death, but neither the researchers nor the intensive care doctors know whether this is the case. For this study we will include 180 patients who are within 48 hours of being admitted to an ICU and meet certain criteria.

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## Does my relative/friend/partner have to take part?

No. We are asking you to advise on the views and feelings you believe your relative/friend/partner would have towards taking part in this study. It is up to you to decide whether or not you wish to provide us with this advice. If you do not wish to give this advice, then a nominated consultee (a doctor who is independent of the study) may be approached for their advice.

If you advise us that, in your opinion, your relative/friend/partner would have no objection to taking part in the study, you will be asked to sign a consultee declaration form stating this. You are still free at any time to request your relative/friend/partner is withdrawn from the study without giving a reason.

If you advise us that, in your opinion, your relative/friend/partner would object to taking part in the study, the standard of care they will receive will not be affected.

## What will happen to my relative/friend/partner if they take part?

Patients who join the study will have an equal chance of being put into one of two possible treatment groups. It is not possible to know beforehand which group they will be in; this will be decided by chance. All patients in both groups will be given standard treatments, for example help with breathing from a ventilator, antibiotics to treat infection, and tube feeding, as normal.

In one group of patients (the intervention group), we will stop giving 'routine' fluids through a drip, but the doctors will still use fluid drips when they think it is needed. Once they are stable, patients in this intervention group will then be given a specific combination of diuretic drugs for up to 3 days. Patients in the other group (the control group) will receive standard care in ICU, which will include the routine use of fluids and/or diuretic drugs according to usual practice. This type of study is called a pragmatic, open, randomised trial, and it ensures that the treatment is tested fairly.

Your relative/friend/partner's medical notes will be reviewed daily by the doctors and nurses from the research team, and some data extracted from the notes to a separate database, to find out if the treatment that your relative/friend/partner has received has had any effect.

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Patients in ICU are monitored closely and have frequent blood tests. As part of the study, to give us more information about how your relative/friend/partner's body is working, we may undertake the following extra tests in some patients in the study <delete if not applicable>.

- A monitor of brain oxygen levels, which consists of a painless sticky plastic strip on their forehead
- A monitor of oxygen levels in muscle tissue, consisting of a painless sticky plastic strip on their leg
- Extra blood and urine for further tests. The blood and urine samples will be transferred to a laboratory at the Queen's University of Belfast, where they will be stored and may be used for other studies in the future. Storage of these samples will enable us to undertake more research into critical illness if new knowledge or technology becomes available. We do not know for sure what these future studies will be but they may involve genetic analysis, sharing samples with collaborators abroad or research in collaboration with partners such as commercial companies. If this happens, the samples shared would be anonymous and external investigators or organisations would not be able to identify the patient. Anonymized data collected as part of the study may also be used to understand the sample analyses. You can indicate on the consent form if you agree to let us retain samples for future use in other ethically approved studies.
- Ultrasound scans of their heart (also called an echocardiograph or echo).

Following discharge from ICU your relative/friend/partner's progress will continue to be followed up. Your relative/friend/partner will receive a telephone call, at 6 months after the date of entry to the trial. This will consist of some questions about their physical and psychological health and should take no longer than 20 minutes.

## What are the possible benefits and disadvantages of taking part?

Different ICU doctors practice in different ways, giving different amounts of fluid and diuretic drugs, and we do not currently know what is the best strategy. We hope that taking part in this study will help us achieve a better understanding of the best

approach to use, and thus will contribute to improved treatment of critically ill patients in the future.

Whether the patient is in the study or not, the ICU team will be paying attention to fluid accumulation as normal. Only patients in the intervention group of the study, however, will have our very specific strategy of fluid restriction and diuretics which we hope will reduce fluid build-up more effectively. We hope that this study will take us closer to finding out whether or not this is beneficial.

The main potential complications of our intervention (fluid restriction and diuretic drugs) include injury to the kidneys, abnormal sodium and potassium (salts) levels in the blood, and excessively alkaline blood. All of these complications happen frequently in patients who are seriously ill, no matter how fluid and diuretics are used. Studies so far suggest that there is no increase in kidney injury when less fluid and more diuretics are used, in fact it may even be beneficial. Sodium, potassium and alkali levels in the blood are monitored, often several times a day, for patients in ICU. We will therefore be able to detect any of these abnormalities early, before harm occurs, and have plans in place to take any corrective measures needed, which may mean stopping the diuretics.

## What if something goes wrong?

Every effort will be made to ensure that no patient taking part in this study is put at risk or harmed in any way. It is very unlikely that anything will go wrong as a result of taking part in this study. If you have any concerns about any aspect of this study, you should contact your hospital's Principal Investigator (contact details below), who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the normal Trust Complaints Procedure.

If something does go wrong and your relative/friend/partner is harmed due to someone's negligence, then they may have grounds for a legal action against the HSC Trust. However, the HSC Trust will not be held liable for any harm which occurs if there is no negligence.

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## Would your relative/friend/partner taking part in this study be kept confidential?

Any information collected about your relative/friend/partner during the course of the study will be kept strictly confidential and will only be seen by staff involved in the study from the HSC Trust, the Trial Co-ordinating Centre (Belfast Health and Social Care Trust), and people from regulatory authorities who ensure that studies such as this are carried out correctly. All of them will have a duty of confidentiality to your relative/friend/partner as a research participant. Clinical data will be stored anonymously and securely, and will be transmitted to researchers in the Belfast HSC Trust, Queen's University of Belfast, and University of Toronto for analysis.

Your relative/friend/partner's GP will be contacted by letter to inform the GP of their participation in the study. Because we need to contact your relative/friend/partner after they leave hospital, researchers at the Belfast HSC Trust will need to keep records of their name, address and other contact details. Confirmation of their health status and contact details may also be sought from their GP surgery before they are contacted.

In addition, information held and maintained on the Northern Ireland Electronic Care Record (NIECR) may be used to access data collected routinely during your relative/friend/partner's stay in hospital and to ascertain their long-term health status and contact details for follow-up. This information will be used only for this study and will not be given to anyone else.

Your relative/friend/partner has the right to see their personal health information related to the research study, but they will not be able to review some parts of the information until after the study has finished. When information from the study is published it will not contain any personal information and it will not be possible to identify any individual.

The data from this study will be kept for at least 5 years after its conclusion (medical records will be kept for 15 years), and may be used in other research studies. Any study data retained/used will be anonymised (have all personal identifiers removed) and it will not be possible to identify any individual.

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## What will happen to the results of the research study?

The study is expected to take two years. It is envisaged that publication of the results will follow shortly after this, through medical publications, websites and press releases. At this point we will be happy to forward a summarised version of the principle findings of the results of the study at your relative/friend/partner's request.

## Who is organising and funding the study?

RADAR-2 is being organised by a group of doctors and scientists led by Dr Jon Silversides, a consultant in Intensive Care Medicine at the Belfast City Hospital, and Professor Danny McAuley, who is a consultant and professor in intensive care medicine at the Royal Victoria Hospital, and Queen's University Belfast, Northern Ireland. It is funded by Northern Ireland Health and Social Care Research and Development Division, the British Journal of Anaesthesia, and the Royal College of Anaesthetists. The Sponsor of the study is the Belfast Health and Social Care Trust.

## Who has reviewed the study?

This research has been reviewed by an independent group of people called a Research Ethics Committee (REC), to protect your relative/friend/partner's safety, rights, wellbeing and dignity. This study has been given a favourable opinion by the REC. The ongoing conduct of the study will be monitored by a separate group of doctors and independent members who will monitor all aspects of the research.

## What happens if I have any questions, concerns or complaints about the study?

If you have any questions about your relative/friend/partner's participation in this study or concerns about the way it has been carried out, you should contact your hospital's Principal Investigator or a member of the research team.

## What happens if I don't want my relative/friend/partner to carry on with the study?

You are free to request your relative/friend/partner is withdrawn from the study at any time and without giving a reason. This will not affect the standard of care they

receive. Your study doctor can take them out of the study at any time if it is in their best medical interests to stop their participation.

If you have any questions that remain unanswered, the study doctor or research nurse will be happy to answer these for you. If you require any further information you may contact your hospital's Principal Investigator or the Trial Co-ordinating Centre as below.

**Thank you for taking the time to read this Information Leaflet.**

## CONTACT DETAILS:

### Principal (Site) Investigator:

Name: «*name*»
Address: «*address*»
«*address*»
«*address*»
«*address*»
Telephone: «*Telephone*»

### Trial Co-ordinating Centre:

Chief Investigator: Dr Jon Silversides

Address: Belfast Health and Social Care Trust
Intensive Care Unit
Lisburn Road
Belfast,
BT9 7AB
Telephone: 028 95 041096

### Complaints / Concerns:

Name: «*name*»

Address: «*address*»
«*address*»
«*address*»
«*address*»

Telephone: «*Telephone*»

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## PERSONAL CONSULTEE DECLARATION

**Regarding patient (*insert patient's name*):**

_____

**Please initial each box**

1. I confirm that I have read and understood the Information Sheet for the above study and have had the opportunity to ask questions and discuss the study. ☐

2. I understand that I am being asked to advise on the views and feelings I believe my relative/friend/partner would have towards participation in the above study. In my opinion they would have no objection to taking part in this study. ☐

3. I understand that I can request my relative/friend/partner is withdrawn from the study at any time, without giving any reason and without their medical care or legal rights being affected. ☐

4. I understand that sections of my relative/friend/partner's medical notes may be inspected by researchers from the NHS Trust, Belfast HSC Trust, or regulatory authorities, where it is relevant to their taking part in this research. I agree to information related to this research being retained, in anonymised form, at the NHS Trust, Trial Co-ordinating Centre (Belfast HSC Trust), the Queen's University Belfast, and the University of Toronto and used in other research studies if required. ☐

5. I understand that the Trial Co-ordinating Centre (Belfast HSCT) will keep records of my relative/friend/partner's name and contact details and may access the Northern Ireland Electronic Care Record to collect routine health information, and to ascertain their health status and contact details for the purpose of follow-up. ☐

6. I understand that my relative/friend/partner will have 'routine' fluid administration discontinued and diuretic drugs commenced if randomised to do so. ☐

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7. I understand that my relative/friend/partner may have additional tests performed as part of the study, including:
   - a monitor of brain oxygen levels* ☐
   - A monitor of oxygen levels in leg muscle* ☐
   - Extra blood and urine for tests* ☐
   - Ultrasound scans of their heart* ☐

   *delete as applicable

8. I understand that blood/urine samples collected for the study from my relative/friend/partner will be stored anonymously at Queen's University of Belfast and may be used for future studies subject to ethical approval. Such research may include sharing samples with research collaborators in other countries and commercial companies, or genetic analysis. ☐

9. I understand that my relative/friend/partner will be contacted 6 months after randomisation, and followed up where necessary, to complete a telephone questionnaire. ☐

10. I understand that my relative/friend/partner's consent will override my advice, when they can give informed consent. ☐

11. I agree to my relative/friend/partner's GP being informed of their participation in the study and being contacted to ascertain their health status and contact details for follow-up purposes. ☐

I am the patient's: _____

*(please write your relationship to the patient here, e.g. wife / brother / partner etc.)*

| **Name of Personal Consultee** | **Signature** | **Date (dd/mm/yy)** |
|---|---|---|
| | | |

| **Name of person undertaking consultation** | **Signature** | **Date (dd/mm/yy)** |
|---|---|---|
| | | |