Sugar or Salt (SOS) trial: Comparing two current treatments for patients with a brain injury

[Local hospital logo to be inserted]

Invitation to take part in a research study

- We are approaching you because your relative has been admitted to hospital with a brain injury and is part of an ongoing research study being run at intensive care units. We would like to ask for your permission for your relative to continue to take part in this research study.
- Throughout this information sheet we use the term 'relative' but this information also applies to partners, close friends or other relations (e.g. if you are a carer).
- Before you make a decision, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and other family members if you wish.
- We ask you to consider your relative's views and feelings, and to set aside your own, when making a decision.
- Your relative continuing in the study is entirely optional, and you do not have to provide consent if you do not wish to. If you do not want your relative to continue to take part, this will not affect the care they receive from their doctors.
- Ask us if there is anything that is not clear or if you would like more information.

How to contact us

If you have any questions about this study, please talk to the doctors who organise it:

[PI contact details]

Tel: XX

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Important things that you need to know

- We want to find the best way to treat patients where the brain swells after a head injury.
- We are comparing two different drugs, which are mannitol and hypertonic saline.
- Both of these drugs are normally used to treat patients with a brain injury, but we do not know which is better for patients.
- You can request that your relative stops taking part in the study at any time

Why is my relative already in this study?

The study is being run at lots of different Intensive Care Units across the UK. When your relative was admitted to the Intensive Care Unit with a head injury they needed to be treated urgently in order to reduce the swelling in their brain. As they were unconscious it was not possible to ask about their views on taking part in the study. Because they needed to be treated urgently it was also not possible to consult you beforehand to ask for your consent on their behalf as this would have delayed their emergency treatment. In these situations doctors are allowed to include patients in studies like this under the Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations 2006.

Now that the initial emergency has passed, we would like to ask for your consent for your relative to continue in the next phase of the research study.

What would taking part involve?

Doctors would normally give either mannitol or hypertonic saline to patients to reduce brain swelling. As part of the study, your relative will have been allocated by chance, using a computer programme, to receive either mannitol or hypertonic saline as part of their treatment.

Your relative will have received, and will continue to receive all other treatments and monitoring as part of standard care. There are no further study-related treatments required.

In total, 638 patients will be involved in the study. Half of the patients will receive the salty solution (hypertonic saline), and half of patients will receive the sugary solution (mannitol).

The study team will keep in contact with you or your relative for 12 months to find out how well they are recovering over time. Researchers will also calculate how much each treatment costs and compare this to how beneficial they were.

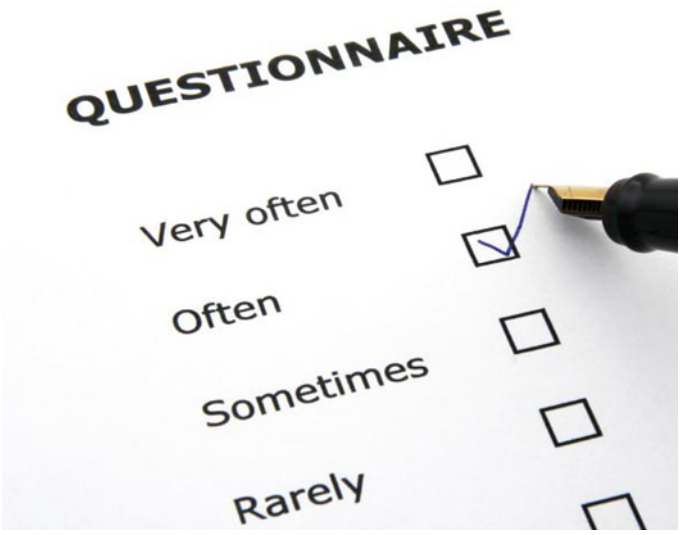
The follow-up will be done in two ways:

1. We will provide you/your relative with a short questionnaire at 3 months, 6 months and 12 months after their brain injury, via post and/or a text message link to an online form to find out how they are recovering. We will also send a gift voucher with each questionnaire as a thank you, but there is no obligation for you to complete or return the questionnaires. These questionnaires should take around 10-15 minutes to complete. If we do not receive a response to the questionnaire, a member of the research team may telephone you/your relative to collect the information over the phone.

2. We will collect data on your relative's health, and information about their hospital stay from NHS medical records and from other organisations (these are listed later in this leaflet on page 8) over the next 12 months.

If you agree for your relative to continue taking part in the study, you will be asked to sign a written consent form. If your relative becomes able to give informed consent themselves during the course of the study, we will give them information about the study and ask whether they would like to continue with the study follow-up.

The study is expected to take around four years to complete. When the study finishes we will contact you/your relative to ask whether you/they would like to receive a copy of the study results.



What are the possible benefits of taking part?

Doctors do not know which of the two treatments is better, and that is why we are conducting this research. We therefore cannot promise any direct benefits as a result of taking part in this study. However it is hoped that the research will provide benefit to future patients who have a severe brain injury, as it will help doctors to know which is the best treatment to give.

What are the possible disadvantages of taking part?

The risk of harm from taking part in the study is not considered to be any higher than the risks of standard clinical care, because we are testing two existing treatments rather than a new treatment.

Because the study involves completing questionnaires, there is a risk that you or your relative may find it upsetting to answer some questions about their recovery. Our trained research staff can talk to you or your relative about any such feelings and can suggest professional services for further support if this would be helpful.

Being part of the study will require a modest time commitment to complete the questionnaires (around 10-15 minutes for each questionnaire). However the information we collect will be very helpful to help us know how best to treat patients in the future.

What if something goes wrong?

If you have a concern about any aspect of this study you should ask to speak to the researchers who will do their best to answer your questions **[PI contact number].**

You can also seek advice from your local Patient Advice and Liaison Service (PALS). They can be contacted at **[insert local PALS contact details]**

If you remain unhappy and wish to complain formally, you can do this by contacting the person below, who is a senior University of Warwick officia and is independent of this study.

Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Tel: 02476 575733
Email: researchgovernance@warwick.ac.uk

This study is covered by the NHS and University of Warwick's insurance and indemnity cover.
Any complaint about the way you or your relative has been dealt with during the study or any possibl harm they may have suffered will be addressed.

If you wish to raise a complaint on how we have handled your relative's or your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

In the event that something does go wrong and you relative is harmed during the research and this is due to someone's negligence then you/your relative may have grounds for a legal action for compensation against the University of Warwick or the relevant NHS organisation but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

What will happen if I change my mind?

The decision for your relative to continue in the research is entirely voluntary and you can change your mind at any time without having to give a reason.

If you do not want your relative to continue to take part in the study, or you change your mind at a later stage, this will not affect the care they receive from the NHS.

If you decide that you want your relative to be withdrawn from the study we will not send any questionnaires to be completed. However we will continue to collect information about your relative's health from other sources (please see page 8) unless you specifically request that we do not. To withdraw from data collection, please contact the study team at **sostrial@warwick.ac.uk** or write to SOS Trial, Warwick Clinical Trials Unit, University of Warwick, Gibbet Hill Road, Coventry, CV4 7AL

You/your relative's rights to access, change or move their information are limited, as we need to manage your relative's information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw your relative from this study, we will keep the information that has already been collected. To safeguard your/your relative's rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of this study?

Our patient and public partners will help us ensure that the findings of the research are summarised clearly. We will share the findings of the research widely. Our plan includes sharing the results with patients, the public, doctors and nurses.

We will do this through talks, social media, written reports and scientific publications. We will work closely with our colleagues in professional organisations to ensure that the findings of this study are included in NHS clinical guidelines.

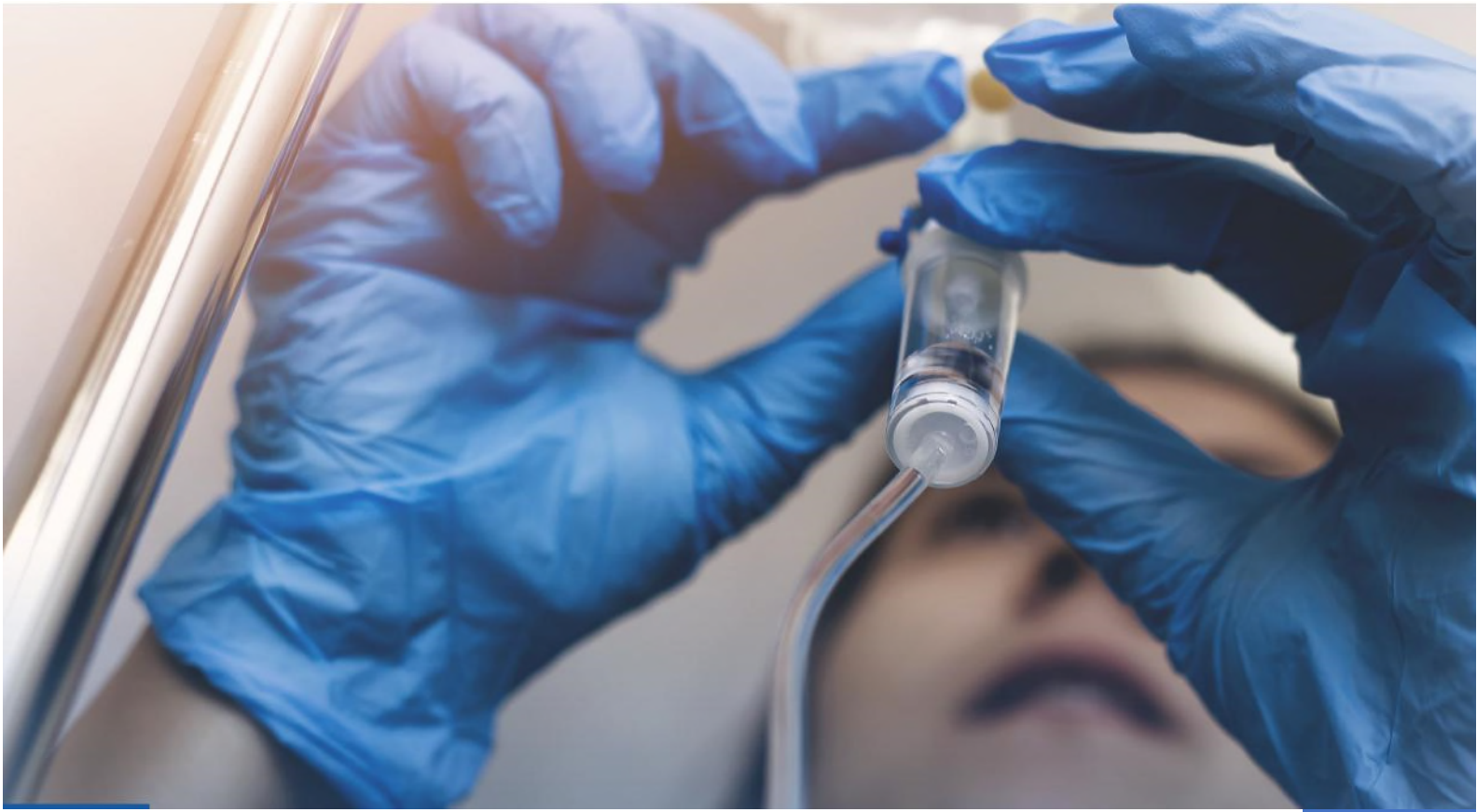
It will not be possible to identify you or your relative in any publications which result from this research.

How have patients and the public been involved in this study?

We are working closely with Headway, a national charity which supports people who have suffered severe brain injuries. They have helped us ensure that the patient and carers perspectives remain central to how the research is designed, conducted, analysed and shared with others. Patient and public representatives have agreed to work closely with us as part of the research team.

Who has reviewed this study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect patients' safety, rights, wellbeing and dignity. This trial has been reviewed and given a favourable opinion by the East of England - Essex Research Ethics Committee. The trial has also been reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA) and National Institute for Health and Care Research (NIHR) Health Technology Assessment Board.



Who is organising and funding the research?

The University of Warwick will coordinate the delivery of this study. University Hospitals Birmingham and the University of Warwick are cosponsors of the study.

This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (Ref: 17/120/01).

FUNDED BY
NIHR | National Institute for Health and Care Research

What information do you collect? Will my relative's information be kept confidential?

As a publicly funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree for your relative to take part in a research study, such as this, we will use your relative's data in the ways needed to conduct and analyse the research study.

We will be using information from your relative and their medical records in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Warwick and the hospital where your relative is/was treated will keep identifiable information about you and your relative at least 10 years after the study has finished.

NHS hospital staff will collect information from you, your relative and their medical records for this research study in accordance with the University of Warwick's instructions.

NHS hospital staff will use your relative's name, NHS number and your/your relative's contact details (address, telephone number, email address) to contact you/your relative about the research study, to make sure that relevant information about the study is recorded for your relative's care, and to oversee the quality of the study. NHS hospital staff will pass these details to the University of Warwick, along with the information collected from you, your relative and their medical records.

By agreeing for your relative to take part in this study, their General Practitioner (GP) may be informed of their participation.

The only people in the University of Warwick who will have access to information that identifies you/your relative will be people who need to:

- audit the data collection process
- collect data from the organisations listed below
- contact you/your relative in order to:
  - send follow-up questionnaires to be completed and contact you/them about any missing information on the questionnaires
  - alert you/your relative that a questionnaire is on its way or has not been completed
  - tell you/your relative about the results at the end of the study

Text messages to alert you/your relative that a questionnaire is on its way or has not been completed will be sent using a third party text messaging service called Esendex. We will share your/your relatives phone number with Esendex but no information that would identify you/your relative by name. Your/your relatives phone number will only be used to contact you/your relative about this study. Further information on Esendex's privacy policy can be found here: https://www.esendex.co.uk/information-security-statement/

The University of Warwick will collect information about your relative for this research study from the following sources:

- their General Practitioner (GP)
- people involved in your relative's care and rehabilitation
- NHS England
- Patient Episode Database for Wales (if your relative resides in, or is treated in, Wales
- Information Services Division Scotland, part of NHS National Services Scotland (if your relative resides in, or is treated in, Scotland)
- Health and Social Care Northern Ireland (if your relative resides in, or is treated in, Northern Ireland)
- Intensive Care National Audit and Research Centre (ICNARC)

This information will include their name, date of birth, NHS number, address, and health information, which is regarded as a special category of information. This health information will include clinical information about diagnoses, treatments given and current health status, administrative information such as dates and methods of admission and discharge, and geographical information such as where they are treated and the area where they live.

We will use this information to follow-up on how your relative recovers, and to find out the costs of treatment during their hospital stay and after discharge.

Individuals from the University of Warwick and regulatory organisations may look at your relative's medical and research records in order to check the accuracy of the research study. Individuals from NHS England and ICNARC may look at research records for audit purposes.The people who analyse the information will not be able to identify your relative and will not be able to find out their name, NHS number or contact details. You can find out more about how we use your/your relative's information here: **https://warwick.ac.uk/services/ idc/ dataprotection/privacynotices/ researchprivacynotice**

When agreeing to take part in a research study, the information about your relative's health and care may be provided to researchers running other research studies at the University of Warwick and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your relative's information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify your relative and will not be combined with other information in a way that could identify them. The information will only be used for the purpose of health and care research, and cannot be used to contact your relative or to affect their care. It will not be used to make decisions about future services available to your relative, such as insurance.

Thank you for taking the time to read this information leaflet.