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 the patient has been admitted to hospital with a brain injury and is part of an ongoing research study being run at intensive care units. As there is no suitable personal legal representative available, we would like to ask for your permission as a professional legal representative for the patient to continue to take part in this research study.
- 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.
- We ask you to consider the patient's views and feelings, and to set aside your own, when making a decision.
- The patient 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 the patient 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

Contents

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 the patient stops taking part in the study at any time.

Why is the study being conducted?

Over one million people each year suffer injuries to their heads which are severe enough that they need to go to hospital.

With the most severe injuries the brain often swells. If this swelling is not treated then the pressure in the skull can get too high, which compresses the brain and causes further damage to the brain.

The main treatments for swelling of the brain involve:

- putting the patient into a coma using drugs (to rest the brain)
- giving drugs (to reduce brain swelling)
- in some cases brain surgery (to release the pressure).

If initial treatments do not work, two drugs are commonly used to treat brain swelling:

- A salty solution (hypertonic saline)
- A sugary solution (mannitol)

Usually doctors would give one of these drugs, or a combination of both, but doctors do not yet know which treatment works best.

Both drugs also have unwanted side-effects. For example, hypertonic saline may affect the balance of salts in the blood, and mannitol may cause damage to the kidneys.

When doctors do not know which treatment is best, it is common to undertake a research study, to make sure that future patients have the best possible outcome after a brain injury. These studies involve putting patients into two groups, where one group will receive one treatment (in this case hypertonic saline) and the other group will receive a different treatment (in this case mannitol). The results are then compared to see if one is better. To try to make sure the groups are the same to start with, each patient is randomly allocated (by chance) to one of the groups.

This study is being conducted to compare how effective hypertonic saline and mannitol are for reducing the pressure in the brain. It will also measure which drug is better at helping the patient to recover, and what the side effects of each treatment are.

Why is the patient already in this study?

The study is being run at lots of different Intensive Care Units across the UK. When the patient 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 a legal representative beforehand to ask for their 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 the patient 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, the patient will have been allocated by chance, using a computer programme, to receive either mannitol or hypertonic saline as part of their treatment. The patient 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 the patient (if they regain capacity) or their 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.

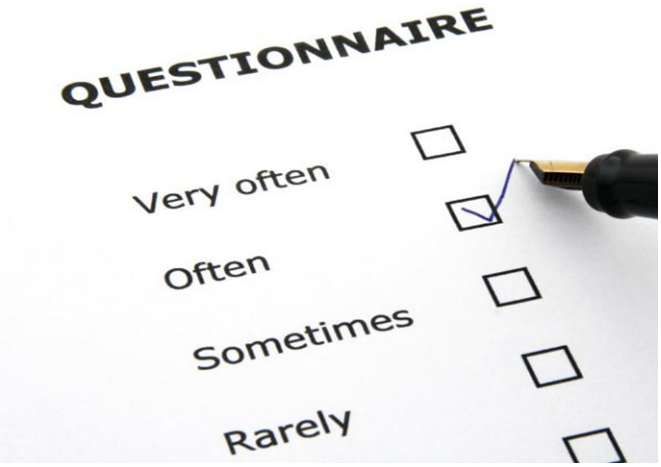
The follow-up will be done in two ways:

1. We will provide the patient (if they regain capacity) or their relative with a short questionnaire at3 months, 6 months and 12 months after their brain injury, via post or a text message link to an online form to find out how they are recovering. These questionnaires should take around 10-15 minutes to complete. We will also send a gift voucher with each questionnaire as a thank you, but there is no obligation for them to complete or return the questionnaires. If we do not receive a response to the questionnaire, a member of the research team may telephone the patient/their relative to collect the information over the phone.

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

If you agree for the patient to continue taking part in the study, you will be asked to sign a written consent form. If a personal legal representative becomes available, or the patient 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 the patient (if they have regained capacity) or their relative may find it upsetting to answer some questions about the patient's recovery. Our trained research staff can talk to the patient or their 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 official 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 the patient has been dealt with during the study or any possible harm they may have suffered will be addressed.

If you wish to raise a complaint on how we have handled the patient'spersonal 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 the patient is harmed during the research and this is due to someone's negligence then you/the patient may have grounds for a legal action for compensation against the University of Warwick or the relevant NHS organisation but the patient may have to pay the legal costs. The normal NHS complaints mechanisms will still be available to you.

What will happen if I change my mind?

The decision for the patient 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 the patient 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 the patient to be withdrawn from the study we will not send any questionnaires to be completed. However we will continue to collect information about the patient'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/the patient's rights to access, change or move their information are limited, as we need to manage the patient's information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw the patient from this study, we will keep the information that has already been collected. To safeguard the patient'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.

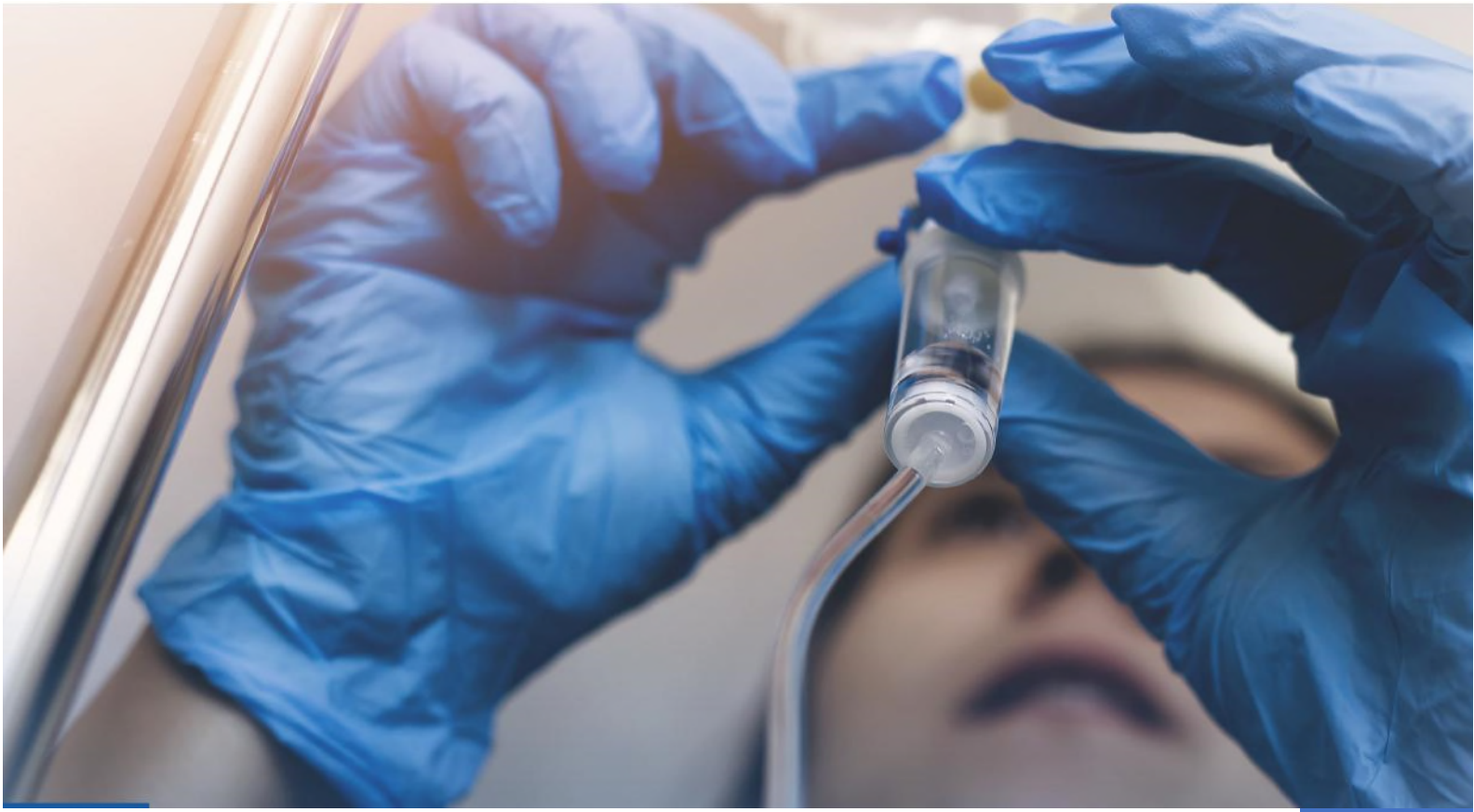
It will not be possible to identify you or the patient in any publications which result from this research

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 co-sponsors 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 the patient'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 the patient to take part in a research study, such as this, we will use their data in the ways needed to conduct and analyse the research study.

We will be using information from the patient 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 the patient is/was treated will keep identifiable information about them at least 10 years after the study has finished.

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

NHS hospital staff will use the patient's name, NHS number and your/the patient's/their relative's contact details (address, telephone number, email address) to contact you/the patient/their relative about the research study, to make sure that relevant information about the study is recorded for the patient'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, the patient, their relative and the patient's medical records.

By agreeing for the patient 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/ the patient and their relative will be people who need to:

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

Text messages to alert you/the patient 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/the patient's phone number with Esendex but no information that would identify you/the patient by name. Your/the patient's phone number will only be used to contact you/the patient 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 the patient for this research study from the following sources:

- the patient's General Practitioner (GP)
- people involved in the patient's care and rehabilitation
- NHS England
- Patient Episode Database for Wales (if the patient resides in, or is treated in, Wales)
- Information Services Division Scotland, part of NHS National Services Scotland (if the patient resides in, or is treated in, Scotland)
- Health and Social Care Northern Ireland (if the patient 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 the patient 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 the patient'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 the patient 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/the patient's information here:
https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice

When agreeing to take part in a research study, the information about the patient'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. The patient'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 the patient 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 the patient or to affect their care. It will not be used to make decisions about future services available to the patient, such as insurance.

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