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A Cluster Randomised Trial of Clinically assisted Hydration in Patients in the Last Days of Life (CHELsea II)

Participant Information Sheet (Arm B)

Sponsor: University of Surrey

Funder: National Institute of Health Research (NIHR131687)

Chief Investigator: Professor Andrew Davies

Principal Investigator at Site: XXXXXXXXXXX

Research Nurse at site: XXXXXXXXXXX

We are inviting you to take part in a research study.

- Before you decide whether or not to take part, we would like you to understand why the research is being done and what it would involve for you.
- Read the following information carefully and feel free to discuss the study with your family, friends, or another health care professional.
- When reading this information sheet, if there is anything that is unclear, please ask your research team to explain.
- You are free to decide whether to take part or not. If you choose not to take part, this will not affect the care you receive from your team.
- If you do take part in the study but change your mind, you are free to withdraw at any time.

Why is this study being undertaken? Important information you need to know.

- When someone is getting close to the end of their life, sometimes it is unclear to doctors and nurses what is the best way to support their fluid intake.
- The aim of this study is to find the best way to treat the majority of people at the end of their life by providing evidence for doctors and nurses in relation to hydration.
- The study will be comparing two accepted standards of care.
- Your medical team will always put your clinical needs before any research activity.

Introduction

Thank you for your time, we would like to invite you to participate in this research study at <<Insert site name>>. You should only participate if you want to and choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

As people get closer to the end of life, they tend to eat and drink less, which may cause more frequent episodes of delirium and agitation as well as other symptoms, which can be distressing for patients, relatives, and friends. The standard treatment for maintaining hydration is to either apply what is known as mouth care, which usually involves applying water or artificial saliva to the lips and in some hospitals and hospices they give the patients fluids by drip either into a vein or under the skin, as well as the mouth care. The different approaches are both standard treatments, but there is no research into which approach works best. The aim of this research study is to provide evidence to allow doctors and nurses to make the right decision in the maintenance of hydration and reduce distressing symptoms such as delirium in the majority of patients.

All the sites in this study will be randomised into one of the two accepted standards of care. The treatment that they use in this study will be decided by chance, 50% of the hospitals and hospices will be encouraging / helping the patient to drink and giving the patient regular mouth care (Group A) and 50% of the hospitals and hospices will be doing exactly the same as Group A, but in addition, giving fluid by a drip (Group B).

The standard treatment in this unit is fluids by drip and regular mouth care (Group B), and we only use mouthcare alone if there is a clinical reason to do so. Your palliative care team have decided that you should receive this treatment (fluids by drip and mouthcare) at the moment and will continue to monitor your condition and may change

this decision based on their clinical judgement. The clinical team, and not the research team, will have the final say in this matter.

This study will see whether the problems experienced at the end-of-life are different in the two groups, and how well patients tolerate the different treatments. The care you will receive will be the same as if you were not in the study. The doctors and nurses routinely collect information on all patients and this information will be shared with the research team at the University of Surrey. The research team will collect the information from your observation chart, drug chart, and medical and nursing notes. The research team will have no direct contact with you during the actual study.

Why have I been invited?

The reason we have approached you about this study is that you seem to be approaching the end-of-life, and are drinking less than normal, or are expected to soon be drinking less than normal. Also, there appears to be no reason not to give you the standard treatment that is used in this hospital / hospice (i.e., fluids by drip). The palliative care team referred you to the research team, as they felt you may be willing to participate in this study.

We are intending to enrol 1600 similar patients to the study from 80 hospitals and hospices in the United Kingdom.

Do I have to take part?

No. It is completely up to you to decide whether or not you wish to join the study. We will describe the study and go through this information sheet before you make any decision. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

What will happen if I take part?

If you decide to take part in the study, then the care you will receive will be the same as if you were not in the study: you will receive fluids by drip, and support with

mouthcare, unless there is a clinical need to change this as directed by your clinical team.

As per usual, the nursing staff will assess you at least every four hours and record any symptoms, drugs, or other treatments you receive, and any problems relating to drinking and regular mouth care. Any issues will be treated in the normal way.

All of the care will be done by your normal doctors and nurses, and you will have no contact with the research team during the actual study. The information collected will be coded (so that your identity is protected), and then sent to the University of Surrey for analysis. The university will not have access to your personal data, only the care team here at [insert site] will have access to this.

What do I have to do?

If you decide to take part in the study, then you will need to sign a consent form to confirm this, a copy of the consent form and this information sheet will be given to you to keep.

Should you lose capacity or become unconscious during the study, your clinical team will talk with your next of kin (person of your choice) and ask their opinion about you remaining in the study. We advise you to discuss this with them before you consent to join the study and make them aware of your feelings and wishes should you lose capacity or become unconscious. This will make sure they know how you feel and what your wishes are.

We will also ask for the name and contact details of your next of kin/consultee (person of your choice). This is so the clinician knows who to talk to if you lose capacity or become unconscious.

Benefits and payments

We cannot promise the study will help you, but the information we get from this study may help to improve the treatment of people with advanced illness in the future.

Neither yourself or your next of kin will be paid for participation in this study.

What are the possible disadvantages and risks of taking part?

Mouth care is sometimes uncomfortable, and if this is the case then the doctors and nurses may decide to stop the treatment altogether.

Inserting the drip can be uncomfortable, and some people may experience bruising / soreness at the site of the drip. Some patients may also experience fluid retention, which may cause swelling of the arms and legs, and sometimes shortness of breath (due to fluid on the lungs). If this is the case, then the doctors and nurses may decide to stop this treatment altogether.

There are no other additional risks or disadvantages in taking part, as this study does not affect the treatment and care that you will receive. Clinical need will always come before the study activities.

Will my taking part in the study be kept confidential?

Yes. All information that is collected about you during the course of the research study will be kept strictly confidential, and any information about you, which leaves the hospital / hospice, will have your name and address removed so that you cannot be recognised. However, there are limits to this, confidentiality will be respected unless there are compelling and legitimate reasons for this to be-overridden e.g., such as duty of care where harm/danger to participants or others may occur or in the public interest.

What if relevant information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, your researcher doctor might consider you should withdraw from the study. They will explain the reasons and arrange for your care to continue.

What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any stage, and you do not have to give a reason. If you do withdraw from the study, your care will not be affected in any way.

Unless otherwise stated the research team will continue to use the clinical information collected up to this time, but they will use any clinical information collected after this.

What if there is a problem?

If you or your next of kin have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to address these.

***Principal Investigator Name**:*

Contact phone number:

Email:

Research Nurse Name (if applicable):

Contact phone number:

Email:

If you remain unhappy and wish to complain formally, you are free to do this through the hospital Patient Advice and Liaison Service (PALS)/ hospice complaints procedure. Details can be obtained from,

Name: Insert Local PALs or contact person at Hospice.

Contact phone number:

Email:

Or

The sponsor, the University of Surrey

Research Integrity and Governance Office (RIGO)

Contact details can be found at the Who is responsible for the study section

The University and the Hospital/Hospice has in place the relevant insurance policies which apply to this study and your care.

Will my data and taking part in this study be kept confidential?

As a publicly funded organisation, we have to ensure that when we use identifiable personal information from people who have agreed to take part in research, that this data is processed fairly and lawfully. The University of Surrey processes personal data for the purposes of carrying out research in the **public interest** and special category data is processed on an additional condition necessary for **research purposes**. This means that when you agree to take part in this research study, we will use and look after your data in the ways needed to achieve the outcomes of the study.

Your personal data will be held and processed in the strictest confidence, and in accordance with current data protection regulations. Personal data is information relating to you, that has the means to identify you directly or indirectly e.g., name, address, contact details. The University will be the data controller. The pseudonymised data will be retained for 10 years, identifiable data will not be sent to the university and be kept for no longer than is necessary at site, the consent forms will be kept with your medical records at this research site.

We will need to use information from your medical records for this research project.

This information will include your [Name/ NHS number/contact details] People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. At no point will personal data be shared with the University; all your personal data will be kept securely at [INSERT SITE] however this personal data may be looked at by individuals from the University of Surrey, from regulatory authorities or from the NHS Trust for monitoring purposes, where it is relevant to my taking part in this research. This will only happen here at site and your personal information will not leave site. I give permission for these individuals to have access to my records.

Where can you find out more about how your information is used?

- by asking one of the research team
- by sending an email to [chelseaii@surrey.ac.uk],
- By contacting our data protection officer dataprotection@surrey.ac.uk
- If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO) (https://ico.org.uk/).

Your rights to access, change or remove your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you wish/decide to withdraw your data from the study, we may not be able to do so. We will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

What will happen to the results of the research study?

We will produce a final report summarising the main findings. We also plan to disseminate the research findings through publication and conferences.

Will my data be used for future research?

When you agree to take part in a research study, the information we collect may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in research in this country or abroad.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research.

As part of the process, with their permission, a person who is closest to you (relative/friend) will be contacted by the research team some point in the future; this is to see if they would like to take part in some related research. The aim of this research will be to get a better understand of their carers experience and improve support for carers in the future. This is completely voluntary and there no expectations or pressure

for them to take part. This study will have all the necessary approvals in place prior to beginning and the data will not be associated with your data from this study.

Funding the research

The research study is being funded by a NIHR (National Institute for Health Research) and HTA (Health Technology Assessment) grant (Award ID NIHR131687).

NIHR Evaluation, Trials, and Studies Coordinating Centre (NETSCC)

University of Southampton

Alpha House

Enterprise Road

Southampton, SO16 7NS

htafunding@nihr.ac.uk

www.nihr.ac.uk/explore-nihr/funding-programmes/health-technology-assessment.htm

Who is responsible for the study?

The University of Surrey is acting as sponsor for the study:

Contact: Research Integrity and Governance Office (RIGO), Research and Innovation Services

Senate House

Guildford, Surrey

GU2 7XH

Phone: +44 (0)1483 683490 / 683890, Fax: +44 (0)1483 683791

rigo@surrey.ac.uk

Who has reviewed the study?

All research in the NHS reviewed by the Health Research Authority (HRA) and an independent ethical committee, to protect your interests. This study has been reviewed and given HRA approval and ethical approval by XXXXXX.

The study has also been reviewed / approved by the NIHR (National Institute for Health Research), the HTA (Health Technology Assessment) and by the University of Surrey.

Thank you for reading this information sheet and for considering taking part in this research. Please keep a copy for your records.