THIRST Alert participant information sheet

We are inviting you to take part in a research project called the THIRST trial
We wish to find out if restricting the total daily oral fluid intake in patients treated for fluid overload has any additional benefit to prescribing medications for patients with your condition of fluid overload. The THIRST trial will help to answer this question by providing randomised recommendations on oral fluid intake or no oral fluid intake using the electronic health care record system that the doctors and nurses use to manage your care.

Why am I being asked to take part in this research?
Your medical team have initiated medication for the treatment of fluid overload in the body but they are uncertain as to whether or not oral fluid restriction would be of additional benefit. After agreeing to include you in the study, your team will have received a randomised recommendation to either: fluid restriction of no more than 1 litre per day or continuing with your usual amount of oral fluid intake.

Although fluid restriction is a commonly used treatment in your condition, its effectiveness in helping to relieve symptoms is unclear. The mainstay of treatment remains medications to help remove excess water and this is unaffected by whether you restrict fluid or not.

Although you are unlikely to receive any direct benefit from taking part, the results of the study may improve the management of patients with a similar condition in the future.

Do I have to take part?
You do not have to take part in the study; you have the right to withdraw at any time. Your decision will not affect the quality of care you receive.

What will I need to do if I take part?
You do not need to do anything as a result of taking part. There are no additional tests or appointments. As part of your usual care, you will be asked how you are feeling and how thirsty you are. There are no extra visits to your doctor over and above those needed for your normal care. The study will last only for the time you are in hospital. The normal processes for your discharge and follow up are unaffected by the study.

How do I opt out?
If you would not like to be included in this study, please let the doctors and nurses looking after you know or alternatively contact the study team directly.

What are the disadvantages/risks?
There are no extra risks involved in taking part in this research. If at any moment you feel like you would like to drink more fluids, you can ask your usual care team for more.

What will happen to information collected about me during the study?
Your medical information will be kept strictly confidential by your doctor. The researchers will only be given as much information from your medical records as is needed for this research and that information will be anonymised. They will not be given your name, where you live or anything that could identify you. The results of this research will be made available to all those taking part who would like to receive it.

Who is organising and funding the research?
T/his study is being carried out by Dr Yang Chen, Dr Anoop Shah, Professor Folkert Asselbergs and Dr Tom Lumbers. It is sponsored by University College London and has support from the Clinical Research Informatics Unit of University College London Hospital (UCLH) and the Biomedical Research Centre at UCLH.

Further Information
You can ask your medical team any questions you may have about the study. You may also obtain more detailed information about this research, including how your medical information will be used, your privacy protected, and the compensation arrangements in the unlikely event that anything goes wrong from the following contacts:

UCLH Patient Advice & Liaison Service (PALS)

Address: PALS

Ground Floor Atrium

University College Hospital

235 Euston Road

London NW1 2BU

Telephone (main hospital): 02034473042

Email: Uclh.pals@nhs.net

Study team contact details:
Dr Yang Chen [Principal investigator: yang.chen@nhs.net]
Dr Tom Lumbers [Chief Investigator: tom.lumbers@nhs.net]
Cardiology Department at UCLH: 020 3447 8066

A description of the study is also available on the following UCLH website, and we plan to publish the study results there too: https://www.uclhospitals.brc.nihr.ac.uk/current-work

Thank you for reading this information.