Version 1.3. 2024-06-10

Research person information for you who were cared for in the intensive care unit for septic shock regarding the study:

Can protocol-directed administration of fluids given for purposes other than circulatory stabilization improve outcome in septic shock?

Entity responsible for research: Region Skåne

Principal investigator: Peter Bentzer, Professor, Senior Physician
Charlotte Yhléns gata 252 23 Helsingborg, 042 - 4061000.

You have been admitted to an intensive care unit and treated for septic shock, a condition caused by an infection in the body. In cases of septic shock, it is common to receive large amounts of fluid. Some of the fluid is given to maintain sufficient blood volume, while some may be given, for example, together with medications or as nutrition. Fluid administration can be life-saving, but research suggests that too much fluid can be harmful. We are therefore carrying out an investigation to see if we can improve the course of care and prognosis for you as a patient by reducing how much fluid is given.

We have let chance determine whether you received a "normal" amount of fluid or a reduced amount of fluid. Since you were very ill, we could not ask if you wanted to participate in the study until now, but we have consulted with your relatives and informed them about your participation in the study.

To study whether the differences in fluid administration between the two groups affect recovery over time, we will contact you by phone about 6 months after you were admitted to the intensive care unit. During this call, we will ask you about your health and how you manage your daily activities. You will also be asked to take a memory test. The call takes just over an hour. If you prefer to visit the hospital, this can be arranged. You are welcome to bring a close friend/relative if you wish. Travel expenses will be reimbursed for both of you.

It is very important for the study that as many people as possible participate in the follow-up, regardless of whether they feel well or unwell. The tests we use to collect information about your recovery have been used in many other studies and can detect even small issues that can affect your recovery and daily life, such as memory problems. If we find that you have persistent

problems, we will ask if you feel you have received the help you needed. If not, we will refer you to an appropriate specialist such as an occupational therapist, physiotherapist, psychologist, neurologist, rehabilitation doctor, or general practitioner for further examination, advice, and support.

All data collected is confidential. It will be coded and stored in an electronic database that meets all confidentiality requirements to protect your privacy. The information is saved for 15 years and no unauthorized person will have access to it. Anonymized data may be shared with foreign researchers.

Participation in the study is voluntary and you can decline participation at any time, upon which further collection of data will be discontinued. You can request that the use of your data be restricted. You also have the right to see what information has been collected and, in the event of any inaccuracies, that they be corrected or completely removed. You are welcome to contact the responsible researchers below at any time if you have questions about the survey. If you are dissatisfied with the way your personal data is processed, you have the right to file a complaint with the Swedish Data Protection Authority (Integritetsskyddsmyndigheten), which is the supervisory authority for this study.

Region Skåne is responsible for your personal data according to the General Data Protection Regulation (GDPR). For questions about how data is handled under the GDPR, you can contact:

> Personuppgiftsombudet i Region Skåne, 291 89 Kristianstad.
>
> Telephone: 044-309 30 00; E-mail: region@skane.se
>
> Patient indemnity insurance applies to this examination.

City, 2020-xx-xx

NN, Job Title

The Clinic for Anesthesia and Intensive Care

XXX XX, Name of hospital
Telephone:
E-mail:

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REDUSE

CONSENT FORM

Can protocol-directed administration of fluids given for purposes other than circulatory stabilization improve outcome in septic shock?

I have been informed about the study both orally and through a written patient information sheet.

I believe that I have had the opportunity to ask questions and that I have had them answered.

I agree to participate in the above study and to my personal data being stored.

I also consent to have the information in my patient record reviewed to see if it matches the information stored in the study database. This review will be conducted by an external study monitor (examiner) to ensure the quality of the study.

Patient

Location: ..... Date: .....

Signature: .....

Name clarification: .....