GODIF

To the Patient

Request for Participation in a Health Science Research Project on Early Treatment of Fluid Overload in Patients Admitted to the Intensive Care Unit

Study Title:
Goal-directed fluid removal with furosemide in intensive care patients with fluid overload – A randomised, blinded, placebo-controlled clinical trial (GODIF).

Introduction

During your admission to the intensive care unit, you were included in the GODIF study, a health science research project. Due to the need for rapid treatment and your medical condition, we were unable to ask for your consent before enrolling you in the study. Instead, two independent physicians (acting as legal representatives) approved your inclusion, and we obtained consent from your closest relative.

We are now asking for your consent to continue participation in the study and to use the data already collected. Participation is voluntary, and you may decline without affecting your current or future treatment.

Before making your decision, it is important that you fully understand the purpose and nature of the study. Please read this information carefully. You will also have a conversation with the responsible investigator or another member of the research team, who will provide additional details and answer any questions you may have. You are welcome to bring a family member, friend, or acquaintance to this discussion. You also have the right to take time to consider your decision.

If you do not wish to participate, the study treatment and data collection will be stopped immediately. However, we will ask for permission to retain and use the data already collected. If you decline this as well, all collected data will be deleted.

Purpose of the Study

We aim to investigate whether early, targeted treatment of fluid overload improves survival chances.

Many critically ill patients develop fluid overload during their stay in an intensive care unit. Several studies suggest that fluid accumulation may increase the risk of death. Therefore, we want to examine whether reducing the duration of excess fluid retention improves outcomes.

The method for removing excess fluid in this study is the same as standard care, but we are adjusting the timing of treatment.

It remains unclear whether fluid overload itself is harmful or whether the most critically ill patients, who already have a lower chance of survival, also accumulate more fluid. In other words, we do not know whether early treatment of fluid overload is beneficial, which is why this study is necessary.

Study Procedure

You were randomly assigned to one of two treatment groups:

- The **study group** receives diuretic medication (furosemide).
- The **control group** receives a placebo (an inactive substance), which in this case is a saline solution.

In the study group, the medication promotes urine output to remove excess fluid. In the control group, the body naturally eliminates excess fluid at its own pace.

Neither you nor the healthcare providers (doctors, nurses, and research staff) know which treatment you received. This blinding ensures that the results are not influenced by expectations or biases. All other treatments remain the same for both groups.

Furosemide, the diuretic used in this study, is a well-established medication that has been used for over 30 years to treat fluid overload. Once the excess fluid is removed, treatment with both the diuretic and placebo will be gradually reduced or stopped in both groups.

After **one year**, we will conduct a follow-up phone call with questions about your health, quality of life, and functional status to assess long-term outcomes.

Study Timeline

We plan to include 1,000 patients in total. If you consent, you will participate in the study for the duration of your intensive care unit stay (maximum 90 days).

Data will be collected on:

- Survival
- Recovery of bodily functions
- Potential side effects of treatment (for up to 90 days)

These data will be extracted from hospital databases and will not require additional procedures.

During the study, we will collect the following data from your medical records:

- Medical history and prior hospital admissions
- Laboratory test results (up to 6 months before admission and throughout the ICU stay)
- Vital signs (heart rate, blood pressure, oxygen saturation, temperature, fluid balance)
- Medications administered
- Use of life-support treatments (mechanical ventilation, dialysis)

Confidentiality and Data Protection

All information will be kept confidential. Your identity will remain anonymous in reports and publications.

The Danish Medicines Agency, GCP unit, and the investigators (sponsor and researcher) may access your full medical record to ensure compliance with study protocols. All individuals with access to your data are bound by confidentiality obligations. The study is registered with the Danish Data Protection Agency, and your consent allows access to your health data for monitoring and quality control purposes.

Potential Benefits

We expect that early diuretic treatment of fluid overload may shorten the duration of excess fluid retention, potentially improving survival chances.

By participating, you had a 50% chance of receiving an early treatment that may be more beneficial than allowing the body to eliminate excess fluid naturally.

The study results will provide important information on treating critically ill ICU patients, benefiting future patients and healthcare systems.

Side Effects, Risks, and Disadvantages

Diuretic treatment for fluid overload is common practice in intensive care units. The only difference in this study is the timing of treatment, so no additional risks are expected.

Known Side Effects of Furosemide

Common and non-serious side effects:

- Electrolyte imbalances
- Dehydration
- Increased urine output
- Temporary increases in triglycerides, creatinine, and uric acid

Rare but serious side effects:

- Allergic reactions
- Decreased platelet, red, and white blood cell counts
- Severe drops in blood pressure
- Pancreatitis
- Skin rash
- Worsening of kidney function
- **Very rarely**: Hearing impairment

There may be unknown risks associated with the study. Please inform us immediately if you experience any health issues during the study.

During the study, we will collect the following data from the patient's medical records:

- Medical history
- Laboratory results (up to 6 months before admission and throughout the ICU stay)
- Vital signs (heart rate, blood pressure, temperature, fluid balance, medication use, and organ support treatments)

The Danish Medicines Agency, the GCP unit, and the responsible investigators (sponsor and investigator) have access to the full medical record to ensure compliance with study protocols. All individuals with access to the records are bound by confidentiality obligations. The study is registered with the Danish Data Protection Agency. Consent includes permission to collect, process, and share necessary health data for quality control and monitoring purposes.

Exclusion and Withdrawal from the Study

You cannot participate if you:

- Are allergic to furosemide
- Experience severe side effects from furosemide

Your participation ends if:

- You are transferred to a non-participating ICU

- The treating physicians decide to withdraw you from the trial
- Unexpected serious complications arise in the study, leading to early termination.

Financial Information

The study is initiated by **Professor and Consultant Morten Bestle** and is funded by:

- Novo Nordisk Foundation (5,082,180 DKK)
- Jakob Madsen and Wife Olga Madsen's Fund (100,000 DKK)
- Grosserer Jakob Ehrenreich and Wife Grete Ehrenreich's Fund (200,000 DKK)
- Svend Andersen's Fund (840,000 DKK)
- Sygeforsikringen Danmark (5,156,965 DKK)

Each participating site will receive 3,000 DKK per included patient to cover recruitment and data collection costs.

None of the investigators have financial ties to companies or foundations that could influence the study results. You will not receive any financial compensation for participation.

Access to Results

The study is expected to conclude by the end of 2027. Results will be published in medical journals and presented at international conferences.

To access study results, visit:
https://euclinicaltrials.eu/ (Search for **2024-512186-14-00**).

For further questions, feel free to contact:

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