

Effects of drinking water quantity and quality on rehabilitation outcomes in critically ill patients

Submission date 24/01/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/01/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Critical illness often leaves patients with long-term physical, emotional, and cognitive challenges even after they leave intensive care. Early rehabilitation during recovery can significantly improve their quality of life. While hydration is a critical component of recovery, current research mostly focuses on how much water is consumed, with limited attention to its quality. This study, called the WAVES Protocol, aims to explore how both individualized hydration strategies and the quality of water affect recovery in critically ill patients during their first month of inpatient rehabilitation. The results could provide new insights into improving hydration practices and rehabilitation outcomes.

Who can participate?

Participants must be aged 18 to 85 and have recently been discharged from an ICU after spending at least five days there due to a critical illness. They should be able to drink fluids either on their own or with minimal support.

What does the study involve?

The pilot trial will include 50 participants (the main study involves 400 participants) randomly assigned to one of four groups: two groups will follow personalized hydration plans, and two will drink water freely without specific guidance. Within each pair, one group will consume artesian spring water, and the other will drink natural mineral water. Personalized hydration plans are designed using advanced tools that calculate water needs based on age, weight, activity level, and other factors. Over four weeks, participants will undergo tests to measure their recovery, including assessments of their ability to perform daily activities, cognitive function, emotional health, and physical strength. Biomarkers in their blood will also be analyzed to understand the role of hydration in reducing inflammation and improving metabolic function.

What are the possible benefits and risks of participating?

Participants may benefit from improved recovery through personalized hydration plans tailored to their individual needs. Additionally, they will contribute to valuable research that could benefit future patients undergoing rehabilitation. Risks include mild discomfort from blood

sample collection and possible side effects from changes in fluid balance, though these will be closely monitored by healthcare professionals.

Where is the study run from?

The study is managed by GREEC (independent research group), based in Germany, with clinical activities taking place at Schön Klinik Bad Aibling in Germany.

When is the study starting and how long is it expected to run for?

January 2024 to January 2029. The study will start recruiting in February 2025 and is expected to last for approximately 24 months, including a pilot phase to ensure feasibility.

Who is funding the study?

The study is funded by Schoen Klinik Bad Aibling and Alpine Water GmbH (i.e., providing the investigational water products).

Who is the main contact?

Marion Egger, PhD, megger@schoen-klinik.de

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

27125

Study information

Scientific Title

Drinking water variability effect study in early rehabilitation

Acronym

WAVES

Study objectives

While the study is exploratory in nature, the primary hypothesis constitutes that a quantitatively individualized hydration regimen improves clinical outcomes in individuals recovering from critical illness. The secondary hypothesis states that drinking water characteristics significantly modify clinical outcomes in individuals recovering from critical illness.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 15/10/2024, Ethics Committee of The Faculty of Medicine at Ludwig Maximilians University Munich (Geschwister-Scholl-Platz 1, Munich, 80539, Germany; +498921800; ethikkommission@med.uni-muenchen.de), ref: 24-0729

Study design

Interventional single-center triple-blind randomized controlled trial and pilot study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life, Treatment, Efficacy

Participant information sheet

Not available in web Format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Critical illness

Interventions

1. Individualized hydration regimens: Patients will receive either individualized drinking water volumes (i.e., bioimpedance, HidrateSmart, bio markers, thirst sensation) or consume drinking water ad libitum.
2. Drinking water characteristics: Participants will either receive either artesian spring water or natural mineral water.

Duration: 4 weeks.

Administration: Per os.

Standard treatment as applicable to both groups: All participants will undergo an inpatient early neurorehabilitation program at a specialized hospital in Germany.

General: 2:2 design; permuted block randomization for pilot, cluster randomization for main study

Intervention Type

Behavioural

Primary outcome measure

Clinical rehabilitation outcomes measured using Barthel Index Scores on days 1 and 28

Secondary outcome measures

1. Cognitive performance measured using the Montreal Cognitive Assessment (MoCA) at baseline, after 2 weeks, and after 4 weeks
2. Depression and anxiety measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, after 2 weeks, and after 4 weeks
3. Sleep Quality measured using the PROMIS Sleep Disturbance Short Form (PROMIS SDSF) at baseline, after 2 weeks, and after 4 weeks

4. Thirst Sensation measured using a 10-point Likert Scale at baseline, after 1 week, after 2 weeks, after 3 weeks, and after 4 weeks
5. Fatigue measured using the Fatigue Severity Scale (FSS) at baseline, after 2 weeks, and after 4 weeks
6. Quality of Life measured using the European Quality of Life 5 Dimensions 5 Level Version (5Q5D5L) at baseline, after 2 weeks, and after 4 weeks
7. Physical Strength measured using the dynamometer test at baseline, after 1 week, after 2 weeks, after 3 weeks, and after 4 weeks
8. Hydration status measured using bioimpedance at baseline, after 1 week, after 2 weeks, after 3 weeks, and after 4 weeks
9. Cardiovascular performance measured using a 2-minute walk test (2MWT) at baseline, after 2 weeks, and after 4 weeks
10. Inflammation measured by quantifying the serum levels of high-sensitivity C-reactive protein (hs-CRP), Interleukin 6 (IL-6), IL-8, tumor necrosis factor (TNF)-alpha, and interferon (IF)-gamma using enzyme-linked immunosorbent assay (ELISA) or multiplex immunoassay at baseline and 4 weeks.
11. Renal function measured by quantifying the serum levels of urea, eGFR (CKD-EPI), electrolytes, albumin, and creatinine using autoanalyzer-based biochemical methods or spectrophotometric assays at baseline and 4 weeks
12. Metabolic function measured by quantifying serum pH, lactate and creatine kinase (CK) using arterial blood gas analysis (for pH and lactate) and spectrophotometric enzymatic assay (for CK) at baseline and 4 weeks
13. Oxidative stress measured by quantifying total antioxidative capacity and glutathione using spectrophotometric assays (e.g., ferric-reducing antioxidant power [FRAP] for total antioxidative capacity) and glutathione-specific fluorometric or colorimetric assays at baseline and 4 weeks
14. Hydration parameters measured by quantifying plasma osmolality using freezing point depression osmometry at baseline and 4 weeks

Overall study start date

10/01/2024

Completion date

27/01/2029

Eligibility

Key inclusion criteria

Subjects must meet all study inclusion criteria as outlined below:

1. Critical illness survivor: Status post ≥ 5 days ICU treatment
2. Ability to ingest adequate amounts of fluid without / with minimal support
3. Age 18 to 85 years
4. All genders
5. Full-term (at least 4 weeks) participation in an inpatient neurorehabilitation program (Schön Clinics rehabilitation program)
6. Cognitive and physiological (i.e., eyesight) ability to perceive and react to visual alarm

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

85 Years

Sex

Both

Target number of participants

50 for pilot (400 for main trial)

Key exclusion criteria

Subjects meeting any of the following exclusion criteria will not be eligible to participate in the study:

1. Current use of PEG or nasogastral tube for TPN
2. Insufficient (German) communication skills to complete the questionnaires
3. Pregnancy/lactation
4. Current malignancy
5. Advanced heart disease \geq NYHA 3
6. Advanced kidney disease and/or dialysis
7. Hyponatremia
8. Participation in other study
9. Palliative care
10. Unwillingness/inability to provide informed consent
11. Unwillingness to follow study protocol (i.e., predominantly consume drinking water for hydration)

Date of first enrolment

27/01/2025

Date of final enrolment

27/01/2027

Locations**Countries of recruitment**

Germany

Study participating centre

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Organisation

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Sponsor type

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ROR

<https://ror.org/04fr6kc62>

Funder(s)

Funder type

Industry

Funder Name

Alpine Water GmbH

Results and Publications

Publication and dissemination plan

Planned publication of study protocol and results in a peer-reviewed journal.

Intention to publish date

01/02/2029

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date