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

Submission date
24/01/2025

Recruitment status
Recruiting

Registration date
29/01/2025

Overall study status
Ongoing

Last Edited
24/03/2026

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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 years 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 90 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 and Schön Klinik Hamburg Eilbek 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 Schön 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

Type(s)
Principal investigator

Contact name
Prof Klaus Jahn

Contact details
Schön Klinik Bad Aibling
Kolbermoorer Str. 72
Bad Aibling
Germany
83043
+49 8061 9030
kljahn@schoen-klinik.de

Type(s)
Scientific

Contact name
Dr Marion Egger

Contact details
Schön Klinik Bad Aibling
Kolbermoorer Str. 72
Bad Aibling
Germany
83043
+49 8061 9030
megger@schoen-klinik.de

Type(s)

Public

Contact name
Mr Simon Göbel

Contact details
Schön Klinik Bad Aibling
Kolbermoorer Str. 72
Bad Aibling
Germany
83043
+49 8061 9030
simon@greec.org

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Efficacy, Quality of life, Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
85 years

Sex
All

Total final enrolment
0

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 ≥ 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
Schön Clinic Bad Aibling
Kolbermoorer Str. 72
Bad Aibling
Germany
83043

Sponsor information

Organisation
Schön Klinik Bad Aibling

ROR
https://ror.org/04fr6kc62

Funder(s)

Funder type

Industry

Funder Name
Alpine Water GmbH

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date