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Is delaying nutrition safe for patients in intensive care?

Submission date	Recruitment status	[X] Prospectively registered
23/01/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
28/01/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/09/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

Contact information

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Scientific, Public, Principal investigator

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Additional identifiers

Study information

Scientific Title
Feasibility And Safety of delaying nuTrition in Intensive Care Units (FAST-ICU) — a multicentre, cluster-randomised cross-over trial

Acronym
FAST-ICU

Study objectives
Primary Objective
Assess the feasibility and safety with regards to hypoglycemia of withholding nutrition and glucose-containing maintenance solutions during the first 72 hours of ICU stay.
Secondary Objectives
• Compare ICU and hospital mortality.
• Compare ICU and hospital length of stay.
• Evaluate effects on:
o glycaemia, insulin need
o occurrence of moderate hypernatremia
o occurrence of refeeding syndrome (RFS), defined as drop of serum phosphate with or without hypokalemia and hypomagnesemia,
o need for organ support therapy (invasive/non-invasive mechanical ventilation, vasopressors, RRT, mechanical circulatory support)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2025, Research Ethics Committee of the University of Tartu (UT REC) (University of Tartu, Grant Office Ülikooli 18a Raekoja plats 9, Tartu, 51004, Estonia; +372 737 6215; eetikakomitee@ut.ee), ref: 406/T-33

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Delaying early (first 72 hours) feeding and glucose-containing maintenance solutions in intensive care patients.

Interventions
Multicentre, open-label cluster-randomised crossover trial with ICU clusters. Each ICU is randomised to one of two sequences: AB (Intervention Control) or BA (Control Intervention). The method of randomisation will be by a computer program (RedCap randomisation module). There will be a 2- to 4-week wash-out/training phase between periods 1 and 2.

Intervention Policy (A): Withhold nutrition and glucose solutions (First 72 h)
• No enteral nutrition (EN) and no parenteral nutrition (PN) for the first 72 hours from ICU admission time (t=0).
• No glucose-containing maintenance IV solutions during the first 72 hours. Balanced crystalloids or normal saline permitted per clinical need.
• 5% glucose solution permitted as vehicle for IV medications as necessary (according to local standard), or as treatment for hypernatremia
• Oral intake permitted ad lib if the patient is awake, willing and able to eat safely.
• Micronutrients: daily vitamins and trace elements are allowed per local practice.
• Protein supplements are not allowed unless part of the standard oral diet.
• Arterial or venous blood glucose measurement every 4h.
• Rescue glucose will be administered according to local protocol.
• After 72 hours, feeding transitions to usual care at clinician discretion (including EN/PN initiation and caloric/protein targets).
Control Policy (B): Standard of Care
• Initiation and advancement of EN/PN and use of glucose-containing maintenance fluids per local practice from admission.
• Arterial or venous blood glucose measurement every 4h.
• Insulin and glycaemic control per local protocols.

Intervention Type
Mixed

Primary outcome(s)
1. Proportion of patients with ≥1 hypoglycemic episode (blood glucose <3.9 mmol/L) within 72 hours measured using data collected from patient medical records at 72 hours after ICU admission

Key secondary outcome(s)
1. ICU mortality measured using data collected from patient medical records at ICU discharge, censored at 90 days

2. Hospital mortality measured using data collected from patient medical records at hospital discharge, censored at 90 days

3. Proportion of patients with severe hypoglycemia (<3.0 mmol/L) measured using data collected from patient medical records at 7 days after ICU admission

4. Daily need for organ support therapies measured using data collected from patient medical records at a daily time point for 7 days after ICU admission

5. Proportion of patients with moderate hypernatremia (> 150 mmol/L) measured using data collected from patient medical records at 7 days after ICU admission

6. Proportion of patients with refeeding hypophosphatemia (phosphate < 0.65 mmol/l and a drop of > 0.16 mmol/l after initiation of feeding) at 7 days measured using using data collected from patient medical records at 7 days after ICU admission

Completion date
30/12/2027

Eligibility

Key inclusion criteria
1. Adult (≥18 years)
2. Intensive Care Unit (ICU) admission (index admission to the participating ICU)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 07/09/2026:
1. The patient requires intravenous glucose infusion, enteral nutrition or parenteral nutrition

according to the attending clinician’s assessment
2. Acute or acute-on-chronic liver failure
3. Moderate hypernatremia (>150 mmol/L)
4. Diabetic ketoacidosis or hyperosmolar hyperglycemic state at admission
5. Pregnancy
6. Exclusive end-of-life care (no other treatment goal than comfort care for end of life)
7. Organ donor
8. Prior enrolment in this trial during the same hospitalisation
9. Patients with a metabolic disease requiring a specific diet and patients with clinical need for a ketogenic diet
10. Patients already enrolled in other interventional studies on nutrition, intravenous fluids, phosphate supplementation or hormonal therapies that influence glucose homeostasis
11. Inclusion not possible due to site-specific regulatory issues regarding the ethical approval or informed consent procedure

Previous key exclusion criteria:
1. The patient requires intravenous glucose infusion according to the attending clinician’s assessment
2. Acute or acute-on-chronic liver failure
3. Moderate hypernatremia (>150 mmol/L)
4. Diabetic ketoacidosis or hyperosmolar hyperglycemic state at admission
5. Pregnancy
6. Exclusive end-of-life care (no other treatment goal than comfort care for end of life)
7. Organ donor
8. Prior enrolment in this trial during the same hospitalisation
9. Patients with a metabolic disease requiring specific diet and patients with clinical need for a ketogenic diet
10. Patients already enrolled in other interventional studies on nutrition, intravenous fluids, phosphate supplementation or hormonal therapies that influence glucose homeostasis

Date of first enrolment
31/08/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Austria

Belgium

Estonia

Germany

Netherlands

Saudi Arabia

Sweden

Switzerland

Sponsor information

Organisation
University of Tartu

ROR
https://ror.org/03z77qz90

Funder(s)

Funder type

Funder Name
Eesti Teadusagentuur

Alternative Name(s)
Estonian Research Council, Estonian Research Council (ETAG), ETAG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Estonia

Funder Name
Tartu Ülikool Kliinikum

Alternative Name(s)
University of Tartu, TÜ

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Estonia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1.0		07/09/2026	No	No