

# Is delaying nutrition safe for patients in intensive care?

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/01/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/04/2026	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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  $\geq 1$  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 ( $\geq 18$  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**

1. The patient requires intravenous glucose infusion according to the attending clinician's assessment

2. Acute or acute-on-chronic liver failure
3. Moderate hyponatremia ( >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**

24/08/2026

**Date of final enrolment**

31/12/2026

## Locations

**Countries of recruitment**

Austria

Belgium

Estonia

Germany

Netherlands

New Zealand

Saudi Arabia

Sweden

Switzerland

United States of America

## 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

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available