Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A Comparison of the ERAS Protocol Including Oral Carbohydrate Supplementation versus the Traditional NPO Approach in Patients Undergoing Total Knee Arthroplasty

Protocol summary

Study aim

To compare the effects of the Enhanced Recovery After Surgery protocol with preoperative oral carbohydrate supplementation versus the traditional nil per os fasting method on postoperative pain and opioid consumption in patients undergoing total knee arthroplasty .

Design

Randomized, parallel, single-center trial. N=78 (39/group). Computer-generated block randomization (4,6), sealed envelopes. Outcome assessor blinded.

Settings and conduct

Single-center trial in operating rooms and orthopedic wards of teaching hospitals of Ahvaz Jundishapur University of Medical Sciences, Iran. Patients undergoing elective total knee arthroplasty receive either the Enhanced Recovery After Surgery protocol with a preoperative carbohydrate drink or traditional nil per os fasting. Participants and care providers are not blinded; the outcome assessor is blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults aged 18 years or older; American Society of Anesthesiologists physical status I–III; scheduled for elective total knee arthroplasty ; able to provide informed consent; able to take oral fluids. Exclusion criteria: Emergency or urgent knee surgery (e.g., surgery for knee fractures or acute conditions); uncontrolled diabetes; severe cardiovascular, renal, or hepatic disease; gastrointestinal disorders or malabsorption preventing oral intake; allergy to carbohydrate solution.

Intervention groups

ERAS group: carbohydrate drink 2h preop plus ERAS protocol. NPO group: standard fasting and conventional care.

Main outcome variables

Postoperative pain intensity; postoperative opioid consumption.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050463N13**
Registration date: **2026-11-01, 1405/08/10**
Registration timing: **prospective**

Last update: **2026-11-01, 1405/08/10**
Update count: **0**

Registration date

2026-11-01, 1405/08/10

Registrant information

Name

Noushin Sarvi Sarmeidani

Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-08, 1405/08/17

Expected recruitment end date

2027-03-08, 1405/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A Comparison of the ERAS Protocol Including Oral Carbohydrate Supplementation versus the Traditional NPO Approach in Patients Undergoing Total Knee Arthroplasty

Public title
Comparing ERAS with a Carbohydrate Drink and Traditional Fasting in Knee Replacement Surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients (≥18 years old) scheduled for elective total knee arthroplasty. Patients physically fit for elective surgery according to the attending physician and classified as ASA I–III. Willingness to provide written informed consent and ability to cooperate with data collection procedures. Ability to orally intake and tolerate oral fluids.

Exclusion criteria:
Patients undergoing emergency surgery or surgery related to knee fractures. Patients with uncontrolled diabetes, severe cardiovascular, renal, or hepatic diseases that may interfere with the ERAS protocol. Patients with gastrointestinal disorders or malabsorption that prevent oral intake of carbohydrate solution. History of allergy or adverse reaction to any component of the carbohydrate solution. Inability or unwillingness to complete the study procedures or postoperative follow-up.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization: Block randomization with variable block sizes of 4 and 6. Unit of randomization: Individual patients. Randomization strata: None (no stratified randomization was used). Tools used in randomization: The random allocation sequence was generated using Sealed Envelope, a secure online randomization service designed for clinical trials. The software was set to produce permuted blocks of sizes 4 and 6. How the random sequence was built: The principal investigator configured the Sealed Envelope system with two treatment arms (ERAS with carbohydrate supplementation and traditional NPO) and variable block sizes (4 and 6). The software then generated a randomization list with sequential subject numbers. The list was exported and used to prepare the allocation envelopes. Allocation concealment: Sequentially numbered, opaque, sealed envelopes were prepared by an independent person not involved in patient enrollment. The envelopes were prepared according to the randomization list generated by Sealed Envelope. Each envelope was opened only after the patient was confirmed eligible and had provided written informed consent. The independent person kept the randomization list confidential until the end of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the nature of the intervention (oral carbohydrate drink versus traditional fasting), participants could not be blinded to their group allocation. The care providers and the principal investigator were also aware of the group assignments because they were responsible for administering the intervention and monitoring patients. However, the outcome assessor responsible for collecting postoperative pain scores (VAS), opioid consumption (MME), and functional assessments was blinded to group allocation. All outcome measurements were performed by a trained assessor who was unaware of whether the patient belonged to the ERAS or NPO group. Data analysis was performed on coded data without group identifiers, so the data analyst was also blinded to group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Vice Chancellery for Research and Technology, 1st Floor, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz

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Postal code
6135715794

Approval date
2026-05-16, 1405/02/26

Ethics committee reference number
IR.AJUMS.REC.1405.207

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis (gonarthrosis) in patients undergoing total knee arthroplasty
ICD-10 code
M17.9
ICD-10 code description
Osteoarthritis of knee, unspecified

Primary outcomes

1

Description
Postoperative pain intensity
Timepoint
Before intervention (baseline) and at 6, 12, 24, 48, and 72 hours after surgery
Method of measurement
Visual Analogue Scale, a 10-centimeter horizontal line with endpoints labeled "no pain" (0) and "worst imaginable pain" (10), administered by a trained outcome assessor

2

Description
Postoperative opioid analgesic consumption
Timepoint
During the first 72 hours after surgery
Method of measurement
Recording all administered opioid analgesics including morphine, fentanyl, and tramadol from medication administration records, and converting them to Morphine Milligram Equivalents for standardized comparison

Secondary outcomes

1

Description
Postoperative hospital length of stay
Timepoint
From the day of surgery until hospital discharge
Method of measurement
Review of medical records and calculation of the number of days hospitalized postoperatively

2

Description
Time to first mobilization and physiotherapy performance
Timepoint
During the first 72 hours after surgery
Method of measurement
Standardized Enhanced Recovery After Surgery protocol checklist and physiotherapy assessment

Intervention groups

1

Description
Intervention group: Enhanced Recovery After Surgery protocol with preoperative oral carbohydrate supplementation. Patients receive a clear carbohydrate-rich drink (400 mL of 12.5% carbohydrate solution) 2 hours before induction of anesthesia. The protocol also includes preoperative patient education, multimodal opioid-sparing analgesia, perioperative local infiltration analgesia, goal-directed fluid therapy, normothermia maintenance, and early postoperative mobilization and oral intake.
Category
Other

2

Description
Control group: Traditional nil per os fasting and conventional perioperative care. Patients fast from midnight before surgery (nothing by mouth) and receive standard perioperative care without preoperative carbohydrate supplementation or Enhanced Recovery After Surgery protocol components.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Nooshin Sarvi-Sarmeydani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abdullah Rafiei
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Nooshin Sarvi-Sarmeydani

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The deidentified individual participant data will not be shared because the study protocol and informed consent form do not include permission for public data sharing. Participant confidentiality is of utmost importance, and

the data will be used solely for the purposes of this study.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study protocol of the randomized controlled trial comparing Enhanced Recovery After Surgery with oral carbohydrate supplementation versus traditional nil per os fasting in patients undergoing total knee arthroplasty. The document includes the full study design, inclusion and exclusion criteria, intervention details, outcome definitions, sample size calculation, randomization method, and ethical considerations.

When the data will become available and for how long

The study protocol will become available after publication of the main results of the trial, and will remain available for a period of 5 years from the date of publication.

To whom data/document is available

The study protocol will be available to researchers working in academic institutions and non-commercial research organizations.

Under which criteria data/document could be used

The study protocol may be used for non-commercial research purposes, including systematic reviews, meta-analyses, and replication studies. Requests will be reviewed by the principal investigator based on the scientific validity and ethical appropriateness of the proposed use.

From where data/document is obtainable

Requests should be sent by email to the principal investigator: Nooshin Sarvi Sarmeydani Email: sarvi.n@ajums.ac.ir Affiliation: Department of Anesthesia, School of Paramedical Sciences, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

What processes are involved for a request to access data/document

Applicants should submit a written request by email stating their name, affiliation, purpose of use, and the intended analysis. The request will be reviewed by the principal investigator within 2 weeks. If approved, the study protocol will be sent electronically within 4 weeks of the request.

Comments