

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Enhanced Recovery After Surgery (ERAS) protocol on isolated tibial fracture surgery's outcome

Protocol summary

Study aim

The effect of preoperative fasting time on the prognosis of isolated Tibial fractures

Design

Patients are divided into Group A and B using a table of random numbers. Each group consists of 43 patients. Group B is the control group.

Settings and conduct

Each group is given fasting time instructions for them. Information on preoperative variables is asked and the required blood tests are ordered. After surgery, patients are asked about the time of the last meal eaten before surgery to be excluded from the study if it is done incorrectly. If done correctly, they will be asked for post-surgery variable information and the required blood tests will be ordered.

Participants/Inclusion and exclusion criteria

All of the patients visiting Sina and Shariati hospitals' emergency room for an isolated tibial fracture during the year 1400 who will undergo surgery will be included. Patients who meet one of the following criteria will be excluded: age below 18 and above 65 years old, not using tourniquet during the operation, pregnancy, multiple trauma, the surgery is performed after 72 hours since hospitalisation, any other concurrent fracture except for Fibular fracture, ASA score above 3

Intervention groups

We plan to change preoperative fasting time from 8 hours for both solid foods and clear liquids to 6 hours for solid foods and 2 hours for clear fluids.

Main outcome variables

Hospitalisation time; Postoperative nausea and vomiting; Preoperative Hemoglobin level, Postoperative Hemoglobin level; Postoperative Blood Sugar (BS) level, Preoperative BS level; Postoperative pain score; Preoperative blood Creatinine level, Postoperative blood Creatinine level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046174N4**

Registration date: **2021-12-13, 1400/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-13, 1400/09/22**

Update count: **0**

Registration date

2021-12-13, 1400/09/22

Registrant information

Name

Hossein Shafiei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

dr_hshafiei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-17, 1400/08/26

Expected recruitment end date

2022-05-21, 1401/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Enhanced Recovery After Surgery (ERAS) protocol on isolated tibial fracture surgery's outcome		Sciences' Sina hospital	
Public title		Street address	
Effect of Enhanced Recovery After Surgery (ERAS) protocol on isolated tibial fracture surgery's outcome		Tehran Sina Hospital, Men's Orthopedic Department	
Purpose		City	
Supportive		Tehran	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Tehran	
Patients visiting Sina and Shariati hospitals' emergency room for an isolated tibial fracture during the year 1400 who will undergo surgery in the same center		Postal code	
Exclusion criteria:		۱۱۳۶۷۶۹۱۱	
Age below 18 years old Age above 65 years old Not using tourniquet during the operation Pregnancy Multiple trauma The surgery is performed after 72 hours since hospitalisation Any other concurrent fracture except for Fibular fracture ASA score above 3		Approval date	
Age		2021-11-17, 1400/08/26	
From 18 years old to 65 years old		Ethics committee reference number	
Gender		IR.TUMS.SINAHOSPITAL.REC.1400.092	
Both		Health conditions studied	
Phase		<u>1</u>	
N/A		Description of health condition studied	
Groups that have been masked		Tibial fracture	
No information		ICD-10 code	
Sample size		M84.36	
Target sample size: 86		ICD-10 code description	
Randomization (investigator's opinion)		Stress fracture, tibia and fibula	
Randomized		Primary outcomes	
Randomization description		<u>1</u>	
Simple randomization is performed using a table of random numbers. In this method, the table of numbers is created without any specific pattern and order, then the numbers in the first column from top to bottom are assigned to the referring patients, respectively. If the number assigned to a patient is odd, that patient enters the intervention group (group A) and if it is even, he/she enters the control group (group B). At the end, each group is given explanations and instructions related to them.		Description	
Blinding (investigator's opinion)		length of stay	
Not blinded		Timepoint	
Blinding description		after release from hospital	
Placebo		Method of measurement	
Not used		days between date of surgery and date of release from hospital	
Assignment		Secondary outcomes	
Other		<u>1</u>	
Other design features		Description	
		Postoperative nausea and vomiting	
		Timepoint	
		One day after surgery	
		Method of measurement	
		Directly asking the patient	
		<u>2</u>	
		Description	
		Postoperative pain score	
		Timepoint	
		One day after surgery	
		Method of measurement	
		Visual Analogue Scale	
		<u>3</u>	
		Description	
		Blood hemoglobin level changes	
		Timepoint	
Secondary Ids			
empty			
Ethics committees			
<u>1</u>			
Ethics committee			
Name of ethics committee			
Ethics committee of Tehran University of Medical			

One day after surgery
Method of measurement
Laboratory evaluation of hemoglobin level before and after surgery

4

Description
Blood creatinine changes
Timepoint
One day after surgery
Method of measurement
Laboratory evaluation of blood creatinine level before and after surgery

Intervention groups

1

Description
Intervention group: They will be instructed to stop eating and drinking all foods except clear fluids(water, light tea and coffee) 6 hours before surgery and stop drinking clear fluids 2 hours before surgery.
Category
Treatment - Other

2

Description
Control group: They will be instructed no to eat or drink any food after 00:00 a.m. the night before surgery.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mohammad Ashouri
Street address
Imam Khomeini st. , S Kargar
City
Tehran
Province
Tehran
Postal code
۱۱۳۶۷۴۶۹۱۱
Phone
+98 21 6312 1417
Email
mohammad.ashouri1@gmail.com

2

Recruitment center
Name of recruitment center
Shariatin hospital

Full name of responsible person
Mohammad Ashouri
Street address
Jalal Al Ahmad st., N Kargar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyed Hossein Shafiei
Street address
Imam Khomeini st. , S Kargar
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Dr_hshafiei@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ashouri

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

Orthopedics

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Latest degree

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Other areas of specialty/work

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available