

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of the enhance recovery after surgery (ERAS) modality effect on mobilization time after spine surgery

Protocol summary

Study aim

Determining the effect of enhanced recovery after surgery protocols on mobility time after spinal surgery

Design

Clinical trial with control group, parallel group, randomized 80 patients 40 patients in the control group and 40 patients in the ERAS group

Settings and conduct

This trial will be conducted on patients who undergo elective spinal surgery, Shariati Hospital, Tehran, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: ≥ 18 years of age and maximum 80 Class 1 to 2 ASA anesthesia Absence of heart failure (EF $< 20\%$) No uncontrolled blood pressure or diabetes No pregnancy Do not use opioids or opioid antagonists in 10 days before Exclusion criteria: Emergent surgery Patient dissatisfaction with continued participation in the study Pregnant women Addict patients

Intervention groups

All patients are monitored under the ASA standard. In the ERAS group, patients will first be given complete oral instruction on the procedure. They will then be provided with an educational pamphlet for further reading. Candidates for surgery who smoke are advised to quit smoking one month before surgery. Patients are allowed to drink carbohydrate drinks the day before surgery up to two hours before surgery. The method of anesthesia will be complete intravenous anesthesia. During surgery, the multi-modal method will be used to perform the drug-free analgesia protocol. To control postoperative pain, 1 gram of acetaminophen is given every 6 hours, and in the case of VAS above 4, a dose of 50 micro fentanyl up to VAS reduction is prescribed below 4. In the control group (8 hours of preoperative fasting), the Foley catheter is routinely implanted. Drugs such as fentanyl are used to control pain.

Main outcome variables

Pain control, nausea and vomiting, length of hospital stay after surgery, time of mobilization after surgery in the

intervention group compared to the control group based on age, and sex.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211023052849N1**

Registration date: **2022-02-01, 1400/11/12**

Registration timing: **prospective**

Last update: **2022-02-01, 1400/11/12**

Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

Arash Heroabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2373

Email address

aheroabadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-14, 1400/11/25

Expected recruitment end date

2022-05-15, 1401/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the enhance recovery after surgery (ERAS) modality effect on mobilization time after spine surgery

Public title

The effect of enhance recovery after surgery (ERAS) modality on mobilization time after spine surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

≥ 18 years of age and maximum 80 Class 1 to 2 ASA anesthesia Absence of heart failure (EF <20%) No uncontrolled blood pressure or diabetes No pregnancy Do not use opioids or opioid antagonists in 10 days before

Exclusion criteria:

Emergent surgery Patient dissatisfaction with continued participation in the study Pregnant women Addict patients

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, individual randomization is used. The sequence of random numbers is generated using "Randomization.com" website with simple randomization method. Finally, the patients are divided into two separate groups by sealed, opaque and sequenced envelopes. Envelopes are no different in size and color. These envelopes, which contain ERAS protocol pamphlets or routine care, are given to the researcher at the clinic. The researcher opens the numbers on the envelope in order for the eligible patients and assigns them to one of the two groups based on the pamphlets and descriptions inside the envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences, School of Medicine

Street address

Keshavarz Blvd, Qarib street

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.129

Health conditions studied**1****Description of health condition studied**

Spine surgery

ICD-10 code

S24.2XXD

ICD-10 code description

Injury of nerve root of thoracic spine, subsequent encounter

Primary outcomes**1****Description**

Pain score

Timepoint

1,2,6,12 ,24 hours after operation-2 days after surgery

Method of measurement

Visual analog scale (VAS)

2**Description**

Nausea and vomiting

Timepoint

1,2,6,12 ,24 hours after operation-2 days after surgery

Method of measurement

Questionnaire and the presence of symptoms

3**Description**

Duration of hospitalization after surgery

Timepoint

24, 48, 72 and 96 hours after surgery

Method of measurement

Patient discharge or continued hospitalization

4

Description

Mobility time after surgery

Timepoint

1,2,6,12 ,24 hours after operation-2 days after surgery

Method of measurement

The patient gets out of bed

Secondary outcomes

empty

Intervention groups

1

Description

The control group will be patients who were candidates for elective spinal surgery and will receive a conventional recovery.

Category

Treatment - Drugs

2

Description

The intervention group will be patients who were candidates for elective spinal surgery and will receive an enhanced recovery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Arsh Heroabadi

Street address

Tehran, North Kargar St., Jalal Al-Ahmad Intersection,
Shariati Hospital

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aheroabadi@sina.tims.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research, Tehran University of
Medical Sciences

Street address

Keshavarz Boulevard, corner of Quds Street, Central
University Organization, sixth floor, Vice Chancellor
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vcr@tums.ac.ir

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

Arash Heroabadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Not all data can be shared.

When the data will become available and for how long

4 months after article publication.

To whom data/document is available

All people

Under which criteria data/document could be used

All analysis are possible on the data.

From where data/document is obtainable

arash.heroabadi@gmail.com Dr Arash Heroabadi, M.D., Anesthesiologist

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

The request will be sent within about 10 days.

Comments