

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of ERAS protocol in outpatient anorectal surgeries

Protocol summary

Study aim

Evaluation of ERAS protocol in outpatient anorectal surgeries compared to traditional method and impact on the quality of life

Design

This study is a prospective and randomized clinical trial.

Settings and conduct

Place of study: Sina Hospital, Tehran University of Medical Sciences Prospective lunch, randomized clinical trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients (18-70) years that agree the letter of satisfaction. 2. ASA class I to III, 3. All patients that underwent fistula surgery with more than 1 cm, internal or external hemorrhoidectomy, hemorrhoidopexia, elective fissure sphincterectomy. Exclusion criteria: 1. Age less than 18 or more than 70 years. 2. Emergency surgery. 3. Patients with kidney or liver failure or transplantation. 4. Pregnant patients. 5. Unsatisfactory. 6. Used opioid or opioid antagonist. 7. Patients that underwent minor surgery, such as: resection of a patch of external hemorrhoid, fistula tract less than 1 cm, peri anal abscess drainage. 8. ASA class IV.

Intervention groups

Intervention group: groups receive ERAS protocol. After admission, these patients receive acetaminophen 1gr and gabapentin 300 mg orally before surgery. The anesthesia is similar control group. After surgery, these group receive acetaminophen (1000 mg q 8h), Ketorolac (10 mg q 8h), and gabapentin (300 mg q 8h) as analgesic. Then both group receive analgesia during 1 week.

Main outcome variables

Evaluation of ERAS protocol in outpatient anorectal surgeries compared to traditional method and impact on the quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201113049373N4**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Ehsan Rahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4443 5556

Email address

dr.rahimpour83@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-24, 1400/12/05

Expected recruitment end date

2022-07-27, 1401/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of ERAS protocol in outpatient anorectal

surgeries

Public title

Evaluation of ERAS protocol in outpatient anorectal surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with age (18-70) years that agree the letter of satisfaction. ASA I to III All patients that underwent fistula surgery with pathway greater than 1 cm, internal or external hemorrhoidectomy, hemorrhoidopexia, elective fissure sphincterectomy

Exclusion criteria:

Age less than 18 or greater than 70 years Emergency surgery Patients with kidney, liver failure or transplantation Pregnant patients Unsatisfactory Used opioid or opioid antagonist Patients that underwent minor surgery, such as resection of a patch of external hemorrhoid, fistula tract less than 1 cm or peri anal abscess drainage.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

Randomization description

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

Ethical committee of Tehran University of Medical Sciences

Street address

Sina Hospital, Hasan Abad square, Imam Khomeini street

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2022-02-12, 1400/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1339

Health conditions studied

1

Description of health condition studied

Anorectal disease

ICD-10 code

K60.5

ICD-10 code description

Anorectal fistula

Primary outcomes

1

Description

Evaluation of ERAS protocol in outpatient anorectal surgeries compared to traditional method and impact of quality of life

Timepoint

Dad and 1400 to More as 1401

Method of measurement

Questionnaire of Post Anesthetic Discharge Scoring System) - visual analogue score & functional pain score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: they receive acetaminophen 1 gr and gabapentin 300 mg before surgery, the anesthesia is like control group. Then, they receive acetaminophen (1000 mg TDS) and gabapentin (300 mg TDS) after surgery. It is noted they give education preoperatively

Category

Treatment - Surgery

2

Description

Control group: they don't receive analgesic before surgery then receive opioid () after surgery. They discharge with oxycodon (5 mg QID until one week).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery ward of Sina Hospital , Tehran University of Medical Sciences

Full name of responsible person

Ehsan Rahimpour

Street address

Sina Hospital, Hasan Abad square, Imam Khomeini street

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Erahimpour@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Rahimpour

Street address

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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

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

Ehsan Rahimpour

Position

Assistant professor of surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

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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

Not applicable

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