Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 3oo 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)
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+98 21 4443 5556
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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 sphicterectomy
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 pach 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 analoge 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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Tehran

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Email
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

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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 scientific inquiries

Contact

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Person responsible for updating data

Contact

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Full name of responsible person
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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