

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effectiveness of enhanced recovery after surgery (ERAS) program compared to the usual protocol on pain severity in patients undergoing surgery for acute appendicitis

Protocol summary

Study aim

Evaluating the effectiveness of enhanced recovery after surgery (ERAS) protocol compared to the usual protocol on pain severity in patients undergoing surgery for acute appendicitis

Design

This study is a randomized controlled clinical trial without blinding. Patients are randomly divided into two separate groups (using a randomly generated sequence using a computer and by sealed, opaque and sequenced envelopes).

Settings and conduct

This trial is conducted on patients with acute appendicitis in Imam Reza Hospital, Mashhad, Iran.

Participants/Inclusion and exclusion criteria

All patients aged between 18-65 years, with acute appendicitis undergoing surgery are included. The exclusion criteria are complicated appendicitis defined with one of these conditions; appendicular peritonitis, appendicular abscess, appendicular phlegmon.

Intervention groups

In one group, patients undergoing routine and standard preoperative care (such as using opioids to relieve pain, placing drains such as NGTube or Foley Catheter, if needed Npo), and in the second group patients undergoing ERAS protocol (such as early feeding, use of NSAIDs as analgesics, reduction of injection fluid volume, etc.) are included.

Main outcome variables

The severity of pain for each patient will be measured based on the Visual Analogue Scale (VAS scale), (between 0 and 10). Finally, the pain score will be divided into three groups: mild (0-2), moderate (3-7) and severe (8-10).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190423043356N2**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Amin Dalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 2557

Email address

daliliam@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of enhanced recovery after surgery (ERAS) program compared to the usual protocol on pain severity in patients undergoing surgery for acute appendicitis

Public title

The effectiveness of enhanced recovery after surgery (ERAS) on pain severity in patients with acute appendicitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-65 Patients with acute appendicitis
Patients undergoing surgery for acute appendicitis

Exclusion criteria:

Appendicular peritonitis Appendicular abscess
Appendicular phlegmon

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

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.

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

Mashhad University of Medical Sciences Ethics Committee

Street address

Ibn-e-sina street, Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2020-01-28, 1398/11/08

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.852

Health conditions studied

1

Description of health condition studied

Acute appendicitis

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

Primary outcomes

1

Description

Severity of postoperative pain

Timepoint

Once, 7 days after surgery

Method of measurement

Visual Analogue Scale (VAS scale)

Secondary outcomes

1

Description

Postoperative Ileus

Timepoint

30 days after surgery

Method of measurement

Physical examination

2

Description

Hospitalization period

Timepoint

During admission

Method of measurement

Number of admission days

3

Description

Postoperative complications

Timepoint

30 days after surgery

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: ERAS program A- Before surgery: limit fasting to 6 hours before surgery, consumption of carbohydrate fluids up to 2 hours before surgery, reducing opioid consumption, reducing the volume of fluid intake to normal volume (normovolemic); prescribing anti-emetic drugs before and after surgery to reduce nausea and vomiting, normal blood sugar during the protocol, avoiding of drain usage, B- Postoperative: early oral feeding immediately after becoming conscious, make the patient to walk as soon as possible to prevent from ileus, administration of non-opioid analgesics to reduce pain and ileus and improve nutrition C- Postoperative follow-up: Evaluation for complications of surgery including wound infection, need for readmission

Category

Treatment - Other

2

Description

Control group: routine care before and after surgery which includes the following : using opioids to relieve pain, using drains such as a nasogastric tube (NG-tube), or Foley catheter, in case of needing to keep the patient in fasting situation (NPO)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Amin Dalili

Street address

Imam Reza Hospital, Ibn-e-Sina St

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daliliam@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice President for Research & Technology, Ghoreschi Building, Daneshgah St

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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amin Dalili

Position

Asistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Surgical Oncology Research Center, Imam Reza Hospital, Mashhad University of Medical Sciences

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

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