

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The comparison of short time outcomes between single incision laparoscopic appendectomy and conventional laparoscopic appendectomy surgery

Protocol summary

Study aim

Comparison of single-incision laparoscopic appendectomy with conventional laparoscopic appendectomy in terms of short-term outcomes.

Design

Clinical trial with a control group, parallel groups, one blinded, randomized, on 28 patients. Used G*Power software for randomization

Settings and conduct

Clinical trial study will be used in this research. The study will be conducted in Imam Ali Hospital of Alborz province and Karaj city To 3 weeks after the operation, information will be collected through a questionnaire and questions from the patient In this single-blind study, the patients will be unconscious during the surgery and will not be informed about which method the surgery will be performed. The research team (interviewers) will know which surgery was performed on which person.

Participants/Inclusion and exclusion criteria

Criteria for entering the research: Consent to participate in the research, age below 20 years, Stable patient
Exclusion criteria from the research: Age over 20 years, abdominal infection, emergency case, pregnancy, perforated appendicitis

Intervention groups

The main intervention is single-incision laparoscopic appendectomy, which is performed randomly for a number of patients under 20 years of age. Also, a number of patients under 20 years of age undergoing routine laparoscopic appendectomy surgery are considered as a control group and for the purpose of comparison with the previous group, and the research will carry out in Imam Ali educational and therapeutic center located in Alborz province, Karaj city in 1401-1402

Main outcome variables

Short-term consequences include beauty of the

operation site; postoperative pain; operation complications (operation site infections, fever, redness and swelling of the abdomen, damage to adjacent organs and bleeding); operation duration; hospitalization time (IV anti biotic therapy time) and the duration of leukocytosis drop

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055027N1**

Registration date: **2022-10-15, 1401/07/23**

Registration timing: **prospective**

Last update: **2022-10-15, 1401/07/23**

Update count: **0**

Registration date

2022-10-15, 1401/07/23

Registrant information

Name

Narges Khaleghi rostamkolaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4410 8369

Email address

atousakhaleghi71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-23, 1401/10/02

Expected recruitment end date

2023-04-22, 1402/02/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of short time outcomes between single incision laparoscopic appendectomy and conventional laparoscopic appendectomy surgery

Public title
The comparison of single incision laparoscopic appendectomy and conventional laparoscopic appendectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the research Age under 20 years Stable patient
Exclusion criteria:
Over 20 years old Abdominal infection Emergency Case Pregnancy Perforated appendicitis

Age
From **1 year** old to **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining informed written consent from the individual and his legal guardian, the allocation of people to treatment groups will be done based on the sequence obtained from the 4 blocks obtained from the address below.
<https://www.sealedenvelope.com/simple-randomiser/v1/lists> Also, the list of random allocation in 7 blocks of 4, which makes 28 people in each group, is as follows: • 1, 4, 1, Group B • 1, 4, 2, Group B • 1, 4, 3, Group A • 1, 4, 4, Group A • 2, 4, 1, Group B • 2, 4, 2, Group A • 2, 4, 3, Group A • 2, 4, 4, Group B • 3, 4, 1, Group B • 3, 4, 2, Group A • 3, 4, 3, Group B • 3, 4, 4, Group A • 4, 4, 1, Group A • 4, 4, 2, Group B • 4, 4, 3, Group A • 4, 4, 4, Group B • 5, 4, 1, Group A • 5, 4, 2, Group B • 5, 4, 3, Group A • 5, 4, 4, Group B • 6, 4, 1, Group B • 6, 4, 2, Group A • 6, 4, 3, Group A • 6, 4, 4, Group B • 7, 4, 1, Group A • 7, 4, 2, Group A • 7, 4, 3, Group B • 7, 4, 4, Group B

Blinding (investigator's opinion)
Single blinded

Blinding description
In this one-sided blind study, the patients will be

unconscious during the surgery and will not be informed about which method the surgery will be performed. The research team (interviewers) will know which surgery was performed on which person.

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences
Street address
Ethics committee office, 2nd floor, Research and Technology Vice-Chancellor, Safarian alley, 45 merti Golshahr
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2022-09-24, 1401/07/02
Ethics committee reference number
IR.ABZUMS.REC.1401.175

Health conditions studied

1
Description of health condition studied
Single incision laparoscopic appendectomy (SILA)
ICD-10 code
K35
ICD-10 code description
Acute appendicitis

2
Description of health condition studied
Conventional laparoscopic appendectomy
ICD-10 code
K35
ICD-10 code description
Acute appendicitis

Primary outcomes

1
Description

The degree of beauty of the operation site

Timepoint

Up to 3 weeks after surgery

Method of measurement

Based on the PSQ questionnaire

2

Description

The amount of pain after the operation

Timepoint

Up to 3 weeks after surgery

Method of measurement

Based on the VAS questionnaire

3

Description

Types of complications after surgery

Timepoint

Up to 3 weeks after surgery

Method of measurement

Self-Report

4

Description

Duration of operation

Timepoint

During surgery

Method of measurement

Based on the duration of surgery

5

Description

Duration of hospitalization

Timepoint

From after surgery to discharge

Method of measurement

Record the number of days of hospitalization

6

Description

Duration of leukocytosis drop

Timepoint

It is measured once before the operation and once or twice after the operation

Method of measurement

Record the duration of leukocytosis drop

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Single-incision laparoscopic appendectomy

Category

Treatment - Surgery

2

Description

Control group: Conventional laparoscopic appendectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Narges Khaleghi Rostamkolaie

Street address

Vali Asr Boulevard, Shura Boulevard, Islamabad, Imam Ali Hospital

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 21 4410 8369

Email

atousakhaleghi71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

Street address

Research and Technology Vice-Chancellor, Safarian alley, Golshahr 45 metri

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3922

Email

Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Narges Khaleghi Rostamkolaie

Position

intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No 2, 1st sarv, sarv st, east farsad Blv, Taavon Blv.

Shahre Ziba

City

tehran

Province

Tehran

Postal code

1487765415

Phone

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Email

atousakhaleghi71@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Narges Khaleghi rostamkolaie

Position

Intern

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Narges Khaleghi rostamkolaie

Position

Intern

Latest degree

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Phone

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Fax**Email**

atousakhaleghi71@gmail.com

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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