

# 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**

+98 21 4410 8369

**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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**Fax****Email**

atousakhaleghi71@gmail.com

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

Karaj University of Medical Sciences

**Full name of responsible person**

Narges Khaleghi rostamkolaie

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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