

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the Effect of Two Methods of Laparotomy and Laparoscopic Appendectomy on Quality of Life

Protocol summary

Study aim

- Comparison of quality of life in patients undergoing appendectomy by laparotomy and laparoscopy

Design

Randomised, not blinded, two arm parallel group

Settings and conduct

In this clinical trial at Allameh Bohlol Hospital, patients undergoing laparoscopic and laparotomy are randomly selected and their quality of life is compared with SF-36 questionnaire. The quality of life of participants before and one month after surgery will be re-evaluated with the same instrument.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Written informed consent to participate in the study - Literacy for reading and writing - Being alert Lack of perforation of appendicitis and peritonitis and other open or laparoscopic surgical contraindications - Over 18 years old - No chronic disease - Lack of mental retardation - No history of mental illness, sedation and anxiolytics - Lack of experience of a stressful accident in the last 6 months - No drug use Exclusion criteria: - Patient failure to participate in the research process - Occurrence of physical, psychological and social problems for any reason

Intervention groups

A group undergoing laparoscopic appendectomy A group undergoing laparotomy appendectomy

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190606043825N1**

Registration date: **2020-01-30, 1398/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-30, 1398/11/10**

Update count: **0**

Registration date

2020-01-30, 1398/11/10

Registrant information

Name

Hamid Reza Niazkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3830 5189

Email address

niazkar@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Two Methods of Laparotomy and Laparoscopic Appendectomy on Quality of Life

Public title

Comparison the Effect of Two Methods of Laparotomy and Laparoscopic Appendectomy on Quality of Life

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written informed consent to participate in the study
Literacy for reading and writing Being vigilant Lack of perforation of appendicitis and peritonitis and other open or laparoscopic surgical contraindications Not having chronic disease Not having mental retardation No history of mental illness, sedatives and anti-anxiety drugs No history of a stressful accident in the last 6 months Not using drugs

Exclusion criteria:

Not being cooperate in the research process Occurrence of physical, psychological and social problems for any reason

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

A two-group web randomization (www.graphpad.com) is used to create simple random sequences. Random assignment was performed using sequence envelope method (SNOSE). The random assignment process will be performed by a person other than the research team.

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

Ethics committee of Gonabad University of Medical Sciences

Street address

Sento Blv. Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-08-07, 1398/05/16

Ethics committee reference number

IR.GMU.REC.1398.092

Health conditions studied

1

Description of health condition studied

Appendicitis

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

Primary outcomes

1

Description

Quality of life

Timepoint

Before surgery and one month after surgery

Method of measurement

SF-36 Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Laparoscopy appendectomy

Category

Treatment - Surgery

2

Description

Intervention group: Laparotomy appendectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohlol Hospital, Gonabad, Iran

Full name of responsible person

Dr Mohammad Sadegh Ramezani

Street address

Nurse Blv, Gonabad, Iran

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9691793718

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+98 51 5722 3514

Email

ms.ramezani@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Abdoljavad Khajavi

Street address

Seno Blv, Gonabad University of Medical Sciences

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Dr Mohammad Sadegh Ramezani

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

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Full name of responsible person

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potentially unidentified individuals data will be made available after the publication

When the data will become available and for how long

When the research is published online

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

Email ms.ramezani@outlook.com

What processes are involved for a request to access data/document

Email to ms.ramezani@outlook.com Will be sent in a week.

Comments