Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 71 3830 5189

Email address
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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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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Dr Mohammad Sadegh Ramezani
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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