

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of complications and outcomes of three methods of Laparoscopic appendectomy , Single-incision and open appendectomy in pediatric patients

Protocol summary

Summary

The main objective of this investigation is to compare of complications and outcomes of three methods of appendectomy, consist of: 1-Laparoscopic 2-Single-incision 3-open appendectomy, in paediatric age group. Inclusion criteria: age between 8 to 14 years. Exclusion criteria: 1-patients with specific diseases (diabetes, congenital diseases and..) 2-use of Corticosteroid 3-presence of complicated appendicitis (generalized Peritonitis, abscess, phlegmon and gangrenous appendicitis). This study will be performed in 75 patients, which will randomly divided into three groups. The interventions consist of: group 1 undergoes open conventional appendectomy, group 2 will be treated by laparoscopic appendectomy and appendectomy in group 3 will be done using single incision appendectomy. Main outcome measures (variables) consist of: duration of surgery, wound infection, size of the scar and the time of hospital stay. This study will be carry-out in 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703088375N12**

Registration date: **2017-08-07, 1396/05/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-07, 1396/05/16

Registrant information

Name

Seyed Amirkazem Vejdani

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3222 2300

Email address

vejdan_sa@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of complications and outcomes of three methods of Laparoscopic appendectomy , Single-incision and open appendectomy in pediatric patients

Public title

Comparison of three methods of appendectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 8 to 14 years Exclusion criteria: patients with specific disease such as diabetes; congenital diseases; immunosuppressive patients; consumption of Corticosteroid; patients with abdominal pain lasting more than 5 days; patients who have signs of generalized Peritonitis; the appendix complication

such as perforation and Gangrenous appendicitis

Age

From **8 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Birjand University of Medical Sciences

Street address

Ghaffari Street, Birjand University of Medical Sciences

City

Birjand

Postal code

Approval date

2017-03-01, 1395/12/11

Ethics committee reference number

ir.bums.REC.1395.250

Health conditions studied

1

Description of health condition studied

Acute appendicitis

ICD-10 code

K35.8

ICD-10 code description

Acute appendicitis without mention of localized or generalized peritonitis

Primary outcomes

1

Description

Duration of surgery

Timepoint

Starts from skin incision to wound clouser

Method of measurement

Minute

2

Description

Wound infection

Timepoint

The third day , The fifth day

Method of measurement

Number

3

Description

The size of the scar

Timepoint

14 days after surgery

Method of measurement

centimeter

4

Description

Hospital stay time

Timepoint

From admission to discharge

Method of measurement

Day

Secondary outcomes

empty

Intervention groups

1

Description

open appendectomy

Category

Treatment - Surgery

2

Description

Trans-umbilical single incision appendectomy

Category

Treatment - Surgery

3

Description

Laparoscopic appendectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Seyyed AmirKazem Vejdani

Street address

Taleghani street

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tuba Kazemy

Street address

Ghaffari Street , Birjand University of Medical Sciences

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Amir Kazem Vejdani

Position

Specialist in general surgery, Associate professor

Other areas of specialty/work

Street address

Imam Reza hospital

City

Birjand

Postal code

Phone

+98 915 161 3885

Fax

Email

vejdani_sa@bums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Amir Kazem Vejdani

Position

Specialist in general surgery, Associate professor

Other areas of specialty/work

Street address

Ghaffari Street, Birjand University of Medical Sciences

City

Birjand

Postal code

Phone

+98 915 161 3885

Fax

Email

vejdani_sa@bums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

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specialis in general surgery / Associate professor

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Fax

Email

Vejdani_sa@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty