

# 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

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vejdani\_sa@bums.ac.ir

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#### Person responsible for scientific inquiries

#### Contact

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**Position**

Specialist in general surgery, Associate professor

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#### Person responsible for updating data

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Birjand University of Medical Sciences

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**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*