

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Comparison of Appendectomy using Small Access versus Classic McBurney's Incision: A Randomized-Controlled Trial

#### Protocol summary

##### Summary

**Objectives:** We conducted this randomized controlled study to find the complications of open appendectomy using small access incision and compare with the complications of open appendectomy using classic McBurney's incision. **Patients and methods:** Patients with acute appendicitis full filling the study requirements who are hospitalized in 2014 at Besat Hospital, Hamadan University of Medical Sciences are enrolled in this study. Patients are randomly allocated in two groups using simple randomization method with random number table. Patients who undergo open appendectomy using small access incision are considered as the case group (n=45) and the others who undergo open appendectomy using classic McBurney's incision are considered as the control group (n=45). A questionnaire is prepared for each patient. All patients are followed for 6 months after surgery. Data of patients including operative time, days of hospitalization, surgical wound infection, analgesic consumption and satisfaction with wound appearance are recorded and compared between two groups. Data analyses are performed with statistical software (IBM SPSS Statistics for Windows, Version 20.0, IBM Corp., Armonk, NY, USA). Comparisons are made with 2-tailed t test (quantitative data) and the Fisher exact test (qualitative data). Statistical significance is defined by  $P \leq .05$ .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201411288729N7**

Registration date: **2015-10-16, 1394/07/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-16, 1394/07/24

##### Registrant information

###### Name

Seyed Mohammad Reza Javadi

###### Name of organization / entity

Hamadan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1264 0061

###### Email address

mr.javadi@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Hamadan University of Medical Sciences

##### Expected recruitment start date

2014-03-21, 1393/01/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Appendectomy using Small Access versus Classic McBurney's Incision: A Randomized-Controlled Trial

##### Public title

Comparison of Two Different Types of Incision in the Surgery of Acute Appendicitis

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients in whom the appendicitis is documented with ultrasound or computed tomography scan. 2. Patients with the signs and symptoms of acute appendicitis with Alvarado score of more than five. Alvarado score is as follows: - Abdominal pain that migrates to the right iliac fossa - Anorexia (loss of appetite) or ketones in the urine - Nausea or vomiting - Tenderness in the right iliac fossa - Rebound tenderness - Fever of 37.3 °C or more - Leukocytosis, or more than 10000 white blood cells per microliter in the serum - Neutrophilia, or an increase in the percentage of neutrophils in the serum white blood cell count. Tenderness in the right lower quadrant and leukocytosis, are assigned two points, and the six other factors are assigned one point each, for a possible total score of ten points. Exclusion criteria: 1. Patients who are found during the appendectomy surgery that have no appendicitis despite the Alvarado score of more than five. 2. Patients with signs and symptoms of peritonitis and its complications including abdominal guarding, diffuse abdominal rigidity development of ileus paralyticus, shock, acute renal failure, peritoneal abscess, and sepsis.

## Age

From **5 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Patients in both of case and control groups are similar in terms of age, gender and body mass index.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamedan University of Medical Science

##### Street address

Hamedan University of Medical Science, Mahdiye

Blvd.

##### City

Hamedan

##### Postal code

##### Approval date

2014-06-25, 1393/04/04

##### Ethics committee reference number

p/16/35/9/1542

## Health conditions studied

### 1

#### Description of health condition studied

Acute appendicitis

#### ICD-10 code

k35.8

#### ICD-10 code description

Acute appendicitis, other and unspecified

## Primary outcomes

### 1

#### Description

The total amount of analgesic consumption

#### Timepoint

Post-operative period until discharge from hospital

#### Method of measurement

Questionnaire- milligrams

### 2

#### Description

Operative time

#### Timepoint

End of operation

#### Method of measurement

Questionnaire- The time difference between the end and the start of operation/ minutes

### 3

#### Description

Hospital stay

#### Timepoint

At the time of discharge form hospital

#### Method of measurement

Questionnaire- the difference between the days of surgery and discharge from hospital/ days

## Secondary outcomes

### 1

#### Description

Surgical site infection

#### Timepoint

1 week, 1 month, 3 and 6 months after surgery

#### Method of measurement

Questionnaire- discharge or redness or pain in/around surgical wound-examined by the surgeon

## 2

### Description

Patient's satisfaction with scar

### Timepoint

1 month, 3 and 6 months after surgery

### Method of measurement

Questionnaire- patients give score to satisfaction with their scar from one to ten- one is the least satisfaction and ten is the most

## Intervention groups

### 1

#### Description

Small access incision in case group. This is a two centimeters, medial and inferior of right anterior superior iliac spine incision and we use Babkak Forceps in this surgery.

#### Category

Treatment - Surgery

### 2

#### Description

Conventional Mc.burney incision in control group

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat hospital

##### Full name of responsible person

Mohamad Reza Javadi

##### Street address

Besat hospital, Ayatollah Motahari Blvd.

##### City

Hamedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research and Technology  
Hamedan University of Medical Science

##### Full name of responsible person

Heydar Tavilani

##### Street address

Hamedan University of Medical Science, Mahdiye Blvd.

##### City

Hamedan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

#### organization/entity?

Yes

#### Title of funding source

Vice Chancellor for Research and Technology Hamedan  
University of Medical Science

#### 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

Hamedan University of Medical Science

##### Full name of responsible person

Seyed Yahya Zarghami

##### Position

general surgery resident

##### Other areas of specialty/work

##### Street address

Besat hospital, Ayatollah Motahari Blvd.

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##### Postal code

##### Phone

+98 81 3264 0061

##### Fax

##### Email

syzarghami@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Science

##### Full name of responsible person

Seyed Mohamad Reza Javadi

##### Position

General surgeon

##### Other areas of specialty/work

##### Street address

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mr.javadi@umsha.ac.ir

##### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Science

**Full name of responsible person**

Seyed Yahya Zarghami

**Position**

general surgery resident

**Other areas of specialty/work****Street address**

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**City**

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**Postal code****Phone**

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**Fax****Email**

Syzarghami@yahoo.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*