

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Assessing the outcomes of drain insertion in open versus laparoscopic splenectomy or splenorrhaphy in patients who are candidate for spleen surgery: a clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the outcomes of drain insertion in open versus laparoscopic splenectomy or splenorrhaphy in patients who are candidate for spleen surgery. Design: a clinical trial. Setting and conduct: The eligible patients who are candidate for spleen surgery will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: Candidate for spleen surgery Intervention group: Laparoscopic splenectomy or splenorrhaphy. Control group: Open splenectomy or splenorrhaphy. Primary outcome: (a) dehiscence during the first five days after surgery through clinical examination; (b) surgical wound infection during the first five days after surgery through clinical examination; (c) accumulation of non-purulent discharge on the surgical side during the first five days after surgery through clinical examination; (d) formation of sub-diaphragmatic abscess on the fifth day after surgery through CT-scan. Randomization: Non-randomized. Blinding: Not possible.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201612059014N136**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-23, 1395/10/03

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the outcomes of drain insertion in open versus laparoscopic splenectomy or splenorrhaphy in patients who are candidate for spleen surgery: a clinical trial

##### Public title

Assessing the outcomes of drain insertion in open versus laparoscopic splenectomy or splenorrhaphy in patients who are candidate for spleen surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Candidate for spleen surgery

##### Age

No age limit  
**Gender**  
Both  
**Phase**  
2  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **20**  
**Randomization (investigator's opinion)**  
Not randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**  
Randomization: Non-randomized. Blinding: Not possible.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Postal code

6517838695

##### Approval date

2016-05-11, 1395/02/22

##### Ethics committee reference number

IR.UMSHA.REC.1395.123

## Health conditions studied

### 1

#### Description of health condition studied

candidate for spleen surgery

#### ICD-10 code

S36.0

#### ICD-10 code description

Injury of spleen

## Primary outcomes

### 1

#### Description

dehiscence

#### Timepoint

during the first five days after surgery

#### Method of measurement

through clinical examination

### 2

#### Description

surgical wound infection

#### Timepoint

during the first five days after surgery

#### Method of measurement

through clinical examination

### 3

#### Description

accumulation of non-purulent discharge on the surgical side

#### Timepoint

during the first five days after surgery

#### Method of measurement

through clinical examination

### 4

#### Description

formation of sub-diaphragmatic abscess

#### Timepoint

on the fifth day after surgery

#### Method of measurement

through CT-scan

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Laparoscopic splenectomy or splenorrhaphy.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Open splenectomy or splenorrhaphy.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Besat Hospital

**Full name of responsible person**

Dr Vahid Hamzei

**Street address**

Besat Hospital, Shahed Square

**City**

Hamadan

**Email**

dr\_hamzei8007@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Besat Hospital

**Full name of responsible person**

Dr Mahdi Eskandarlou

**Position**

Urologist

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

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-chancellor for Research the Technology,

Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

**City**

Hamadan

**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 the Technology, Hamadan

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**

Besat Hospital

**Full name of responsible person**

Dr Vahid Hamzei

**Position**

Resident of Urology

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

Besat Hospital, Shahed Square

**City**

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**Postal code****Phone**

+98 81 3364 0030

**Fax****Person responsible for updating data****Contact****Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

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

School of Public Health, Hamadan University of

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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*