

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effect of splenectomy with ligasure and conventional splenectomy (silk and suture) in traumatic patients referred to Emam Reza Hospital, Birjand, 2012-13

Protocol summary

Summary

The main objective of this investigation is the comparison of the intraoperative hemorrhage and operation time between two groups of patients (Control and investigation group). All admitted patients with splenic injury (sample size 80 people) were included. Demographic data (gender and age) will be collected by a questionnaire. After planning for splenectomy, patients were divided into two groups randomly. All of the operations will have done by one surgeon. In control group (39 patients) patients will undergo splenectomy using conventional method with silk suture ligation of splenic vasculature. In investigation group (41 patients), a Ligasure vascular sealing system will be used for ligation of the splenic vein and artery. The operation time will be measured from the start of anesthesia process up to the end of recovery. Intraoperative hemorrhage will be measured by collecting the volume of blood in suction bag. The volume of blood that exit from drain will be considered as post-operative hemorrhage. Inclusion criteria are hemodynamic instability and third and more degree of spleen damage in CT scan. Exclusion criteria are BMI>30 and unwillingness to participate in the study. Intervention is method of splenectomy that will be done by means of LigaSure in the intervention group and silk suture in the control group. Main outcome measures (variables) are operation time and intraoperative hemorrhage.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112148375N2**
Registration date: **2012-09-08, 1391/06/18**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-08, 1391/06/18

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

vejdani_sa@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of splenectomy with ligasure and conventional splenectomy (silk and suture) in traumatic patients referred to Emam Reza Hospital, Birjand, 2012-13

Public title

LigaSure application in Splenectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Multiple trauma patients with splenic injury who need splenectomy; Third degree and more splenic injury on abdominal CT scan staging. exclusion criteria: Patients who do not have agreement to participate in study; Body Mass Index (BMI) more than 30.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This is a single blind study and after planning for splenectomy and taking the consent from, patients will be divided into two groups randomly and will not be aware of their treatment method.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghafari Avenue

City

Birjand

Postal code

9717853577

Approval date

2012-02-07, 1390/11/18

Ethics committee reference number

18111390

Health conditions studied**1****Description of health condition studied**

Splenic injury after blunt abdominal trauma

ICD-10 code

S36.0

ICD-10 code description

Injury of spleen

Primary outcomes**1****Description**

Duration of surgery

Timepoint

During surgery

Method of measurement

Duration of surgery will be measured from the start point to the end of the operation.

2**Description**

Intra-operative bleeding volume

Timepoint

During surgery

Method of measurement

Volume of intraoperative bleeding which collected in the suction (ml) and the number of bloody gauzes (each gauze 10 cc and long gauze 60 cc) will be measured.

Secondary outcomes**1****Description**

Post-operative bleeding

Timepoint

Every 6 hours to discharge

Method of measurement

The blood volume collected in drain's bag (cc)

Intervention groups**1****Description**

Intervention group: Splenectomy with Ligasure

Category

Treatment - Surgery

2**Description**

Control group: Conventional splenectomy using sutures

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Educational Hospital

Full name of responsible person

Dr Seyed Amirkazem Vejdan

Street address

Surgery Ward, Emam Reza Educational Hospital,
Taleghani Avenue

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Birjand University of
Medical Sciences

Full name of responsible person

Dr Asghar Zarban

Street address

Vice-Chancellor for Research , Birjand University of
Medical Sciences, Ghafari Avenue

City

Birjand

Grant name**Grant code / Reference number**

664

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

Yes

Title of funding source

Vice chancellor for research, 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

Surgery ward, Emam Reza Educational Hospital,
Birjand University of Medical Sciences

Full name of responsible person

Dr Ghodrat Allah Naseh

Position

General Surgeon/ Chief of surgery ward

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

Surgery ward, Emam Reza Educational Hospital,
Taleghani street

City

Birjand

Postal code**Phone**

+98 56 1222 2300

Fax**Email**

Nasehghodrat@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Surgery ward, Emam Reza Educational Hospital,
Birjand University of Medical Sciences

Full name of responsible person

Dr Seyed Amirkazem Vejdan

Position

General Surgeon

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

Surgery ward, Emam Reza Educational Hospital,
Taleghani street

City

Birjand

Postal code**Phone**

+98 56 1222 2300

Fax**Email**

vejdan_sa@yahoo.com

Web page address

www.surgeryonweb.com

Person responsible for updating data

Contact

Name of organization / entity

Student Research Committee, Birjand University of
Medical Sciences

Full name of responsible person

Seyed Alireza Javadinia

Position

Medical Student

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

Student Research Committee, Birjand University of
Medical Sciences, Ghafari Avenue

City

Birjand

Postal code**Phone**

+98 56 1222 2300

Fax**Email**

sar.javadinia@bums.ac.ir

Web page address

sarjavadinia@blogfa.com

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