

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of a new synthetic, absorbable sealant with current surgical methods to prevent bleeding and air leak in general surgery and thoracic operations

Protocol summary

Summary

Clinical goals of this study include evaluation of a new synthetic, absorbable sealant to prevent bleeding and air leak without using sutures in patients undergoing general surgery and thoracic operations and instruction to the general surgery residents concerning the utilization of a new hemostatic method. Inclusion Criteria of this study consist of abdominal trauma patients with Grade I & II splenic, liver and renal injuries and patients undergoing elective surgical operations such as cholecystectomy or thoracotomy. Patients undergoing neurosurgery and vascular operations in addition to pregnant and lactating women are excluded from the study. During a one-year period 30 patients, according to inclusion criteria, will be entered in the study and intra-operative and postoperative amount of bleeding and/or air leak in addition to the time of hemostasis and the number of possible failed cases will be documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201028588N1**
Registration date: **2012-05-29, 1391/03/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-29, 1391/03/09

Registrant information

Name

Mohadeseh Pishgahroudsari

Name of organization / entity

Minimally Invasive Surgery Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 5447

Email address

research@lapsurg.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences.

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of a new synthetic, absorbable sealant with current surgical methods to prevent bleeding and air leak in general surgery and thoracic operations

Public title

Evaluation of a new material to prevent bleeding and air leaks in general and thoracic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Abdominal trauma patients with Grade I & II splenic and liver injuries; Hemostasis following partial splenectomy; Hemostasis after liver mass resection (eg:metastasis) Liver bed hemostasis following cholecystectomy ;Hemostasis of Grade I & II renal injuries ;Hemostasis following partial nephrectomy for

superficial tumors:Aerostasis after lung Decortication
:Hemostasis of Grade I lung injury :Aerostasis after lung
wedge resection Exclusion Criteria:Neurosurgery
operations :Vascular operations: gastrointestinal
anastomosis: Patients hemodynamic instability: Splaenic,
liver and renal injuries greater than Grade II: Pregnant
and lactating women undergoing surgery

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Corner of
Ghods St., Keshavarz Blvd., Tehran, Iran.

City

Tehran

Postal code

Approval date

2012-04-23, 1391/02/04

Ethics committee reference number

51869

Health conditions studied

1

Description of health condition studied

Abdominal trauma: Liver Mass: Gallstone: Renal Tumor:
Pleural Disease: Lung Injuries.

ICD-10 code

s36.9.c22.

ICD-10 code description

Other injuries of lung: Malignant neoplasm of kidney:
except renal pelvis: Cholelithiasis: Malignant neoplasm:
Liver: unspecified: Injury of unspecified intra-abdominal
organ: Other pleural conditions.

Primary outcomes

1

Description

Amount of IntraOperative Bleeding

Timepoint

During the Intervention

Method of measurement

Millilitre

2

Description

Air Leak

Timepoint

During the Intervention

Method of measurement

Observation(Grade I,II,III)

Secondary outcomes

empty

Intervention groups

1

Description

Using a Medical Sponge Intraoperatively

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool-e-Akram Hospital

Full name of responsible person

Dr.Akbar Fotouhi

Street address

Minimally Invasive Surgery Research Center, Rasool-
e-Akram Hospital, Niyayesh Ave, Sattarkhan St.,
Tehran, Iran.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotouhi

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Minimally Invasive Surgery Research Center, Tehran University of Medical Sciences.

Full name of responsible person

Dr.Mohammad Vaziri

Position

Fellowship of Thoracic Surgery

Other areas of specialty/work

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Person responsible for updating data

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Associate professor of Thoracic surgery

Other areas of specialty/work

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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