

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Randomized clinical trial comparing the effect of Surgicel, TachoSil and Glubran 2 in controlling bleeding after liver resection

Protocol summary

Summary

(1) Objectives: Our aim in this study is to evaluate the efficacy of Surgicel, TachoSil and Glubran 2 in bleeding control after liver resection. (2) Design: 45 patients from both genders undergoing liver resection in Imam Reza Hospital after qualifying the inclusion and exclusion criteria and obtaining the informed consent, the patients enter the trial process. (3) Setting and conduct: All patients with oozing at the end of the surgery after failure to homeostasis using argon beam coagulator and packing with gauze, will receive Surgicel, TachoSil or Glubran 2 over the resection surface to obtain hemostasis. After hemostasis, drain will be implanted. During the admission, daily drainage volume till the drain extraction and vital signs every 6 hours will be recorded. Patients will be discharged if there is no complication. (4) Participants including major eligibility criteria: Participants will be selected among the patients undergoing liver resection. The key inclusion criteria are to be 18-75 years old and the key exclusion criteria are death during surgery; early closure of the surgery; hepatic insufficiency or coagulopathy after surgery; patients with need for re-operation due to bleeding or bile leakage other than resection site; patients with chronic hepatic disease. (5) Intervention: Using Surgicel, TachoSil or Glubran 2 for bleeding control at the end of liver resection. (6) Main outcome measures: Primary endpoint is bleeding volume after using hemostatic agent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031712834N1**

Registration date: **2013-05-01, 1392/02/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-01, 1392/02/11

Registrant information

Name

Mir Salim Seayed Sadeghi

Name of organization / entity

Department of Surgery, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 7054

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seayedsadeghim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial comparing the effect of Surgicel, TachoSil and Glubran 2 in controlling bleeding after liver resection

Public title

Randomized clinical trial comparing the effect of different

homeostatic agents for controlling homeostasis after hepatic resection.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-75 years old; all patients undergoing hepatic resection and have oozing after resection; patients with no coagulation disorders
Exclusion criteria: Death during the surgery; hepatic mass to be none resectable; early closure of the surgery; hepatic insufficiency after surgery; coagulopathy after the surgery; patients with need for re-surgery due to bleeding or bile leakage other than resection site; patients with chronic hepatic disease

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

N/A

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz university of medical sciences, Daneshgah Square

City

Tabriz

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

91214

Health conditions studied

1

Description of health condition studied

Liver metastasis

ICD-10 code

C78.7

ICD-10 code description

Secondary malignant neoplasm of liver and intrahepatic bile duct

2

Description of health condition studied

Malignant neoplasm of liver and intrahepatic bile ducts

ICD-10 code

C22

ICD-10 code description

Malignant neoplasm of liver and intrahepatic bile ducts

3

Description of health condition studied

Topical homeostatic agents

ICD-10 code

Y56.9

ICD-10 code description

Topical agent, unspecified

4

Description of health condition studied

Other diseases of liver in need of surgery

ICD-10 code

K76.8

ICD-10 code description

Other specified diseases of liver

Primary outcomes

1

Description

Bleeding control

Timepoint

Every 6 hours until 48 hours

Method of measurement

Observation during surgery and evaluation of Hb, INR every 6 hours

Secondary outcomes

1

Description

Complications after oozing control

Timepoint

Days 1, 3, 5, 7 after surgery

Method of measurement

Physical examination and paraclinical evaluations

Intervention groups

1

Description

In Surgicel group, Surgicel (a topical cellulose homeostatic agent) in the size of 10*20 cm will be used to control bleeding

Category

Treatment - Drugs

2

Description

In TachoSil group, TachoSil (contains human coagulation factor components: fibrinogen and thrombin) in the size of 4.8*4.8 cm will be used to control bleeding

Category

Treatment - Drugs

3

Description

In Glubran2 group, one Glubran2 glue (N-butyl -2-cyanoacrylate) will be used to control bleeding.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mir Salim Seayed Sadeghi

Street address

Department of Surgery, Imam Reza Hospital, Daneshgah Square

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Seyyed Kazem Shakouri

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square

City

Tabriz

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, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mir Salim Seayed Sadeghi

Position

Surgery resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Assistant Professor/ Visceral Transplant Surgeon

Other areas of specialty/work

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Position

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

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Postal code**Phone****Fax****Email**

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