

# 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

###### Email address

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

#### Street address

Department of Surgery, Imam Reza Hospital,  
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seayedsadeghim@tbzmed.ac.ir

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Department of Surgery, Tabriz University of Medical  
Sciences

#### Full name of responsible person

Dr. Farzad Kakaei

#### Position

Assistant Professor/ Visceral Transplant Surgeon

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Surgery resident

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

Department of Surgery, Imam Reza Hospital,  
Daneshgah Square

**City**

Tabriz

**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*