

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of pain and side effects between sono guided subcostal and intercostal approaches of liver biopsy

#### Protocol summary

##### Study aim

Comparison of pain, bleeding and pneumothorax between two sono guided liver biopsy approaches ( intercostal and subcostal)

##### Design

Patients with indication for liver biopsy randomizes by computerized codes in two groups ( intercostal and subcostal )

##### Settings and conduct

This study was performed in Imam Reza hospital (as a referal center in Mashhad). Patients were randomized by computerized codes in two groups of subcostal and intercostal for liver biopsy and after local anesthesia liver biopsy was performed by skilled interventional radiologist and pain was estimated by VAS score in 0, 2 and 4 hours after biopsy. Bleeding by sonography and pneumothorax by checking of clinical symptoms (dyspnea) and if it was positive by CXR were evaluated .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- clinical indications for liver biopsy 2- normal coagulation status 3- age > 18 Y/O Exclusion criteria : 1- Patient's avoidance to sign informed consent. 2-Platelet level < 70000 or INR > 1. 3-interahepatic biliary duct dilatation 4- severe ascitis . 5- Impossibility of randomization due to patients' lesion conditions 6- Addiction to cigarette or other drugs .

##### Intervention groups

patients were randomized in two groups and our intervention , was type of biopsy approach ( subcostal and intercostal ) .

##### Main outcome variables

pain ; complications ( bleeding and pneumothorax)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180106038249N1**

Registration date: **2018-02-09, 1396/11/20**

Registration timing: **retrospective**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

##### Registration date

2018-02-09, 1396/11/20

##### Registrant information

###### Name

Khaled Hashemi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3321 3819

###### Email address

hashemirk931@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-01-20, 1394/10/30

##### Expected recruitment end date

2017-06-19, 1396/03/29

##### Actual recruitment start date

2016-01-20, 1394/10/30

##### Actual recruitment end date

2017-09-20, 1396/06/29

##### Trial completion date

empty

##### Scientific title

Comparison of pain and side effects between sono guided subcostal and intercostal approaches of liver biopsy

##### Public title

Comparison of pain and side effects (bleeding and

pneumothorax) between subcostal and intercostal approaches of sono guided liver biopsy

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Clinical indication for liver biopsy Normal coagulation status Age > 18 Y/O

#### **Exclusion criteria:**

Patient avoidance to sign informed consent Platelet level < 70000 or INR>1.5 Intrahepatic biliary ducts dilatation Severe ascitis Impossibility of randomization due to patient's liver lesion conditions Addiction to cigarette or other drugs

### **Age**

From **18 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### **Sample size**

Target sample size: **80**

Actual sample size reached: **124**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Patients randomized in two groups ( subcostal and intercostal approach for sono guided liver biopsy) by computerized codes.

### **Blinding (investigator's opinion)**

Triple blinded

### **Blinding description**

Patients did not have information about the approach of liver biopsy ( subcostal or intercostal) and data were given to statistical analyzer only by computerized codes without mention about biopsy approaches .

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Mashhad University of Medical Scinces

### **Street address**

Imam Reza hospital, next to Imam Reza Square, Mashhad, Iran

### **City**

Mashhad

### **Province**

Razavi Khorasan

### **Postal code**

9137913316

### **Approval date**

2016-10-18, 1395/07/27

### **Ethics committee reference number**

IR.MUMS.FM.REC.1395.295

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Pain management in liver biopsy

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Pain score in Visual analogue scale

#### **Timepoint**

Pain measurement at 0, 2 and 4 hours after liver biopsy

#### **Method of measurement**

Visual analogue scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In this group , we use subcostal approach for doing liver biopsy.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: In this group , we use intercostal approach for doing liver biopsy.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Radiology department of Imam Reza hospital

**Full name of responsible person**

Bitra Abbasi

**Street address**

Radiology department, Imam Reza hospital, Next to Imam Reza square, Mashhad, Iran

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**Postal code**

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**Phone**

+98 51 3854 3031

**Email**

AbbasiB@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi (MD)

**Street address**

Research administration of medical faculty, medical university of Mashhad, next to Azadi square, Vakil Abad Blvd, Mashhad, Iran

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mashhad

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**Email**

TafaghodiM@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Bitra Abbasi

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiology

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data including Spilberger Questionnaire and VAS score and rate of complications can be announced.

**When the data will become available and for how long**

Six months after paper publication ( probably September 2017)

**To whom data/document is available**

Available for all people.

**Under which criteria data/document could be used**

After getting permission from reliable medical ethics committee, our data can be available.

**From where data/document is obtainable**

Dr. Bita Abbasi, Radiology assistant professor of Mashhad University of medical sciences. E-mail address : AbbasiB@mums.ac.ir Post address: Radiology department, Imam Reza Hospital , Imam reza square , Mashhad, Iran Postal code : 9137913316 Telephone : +98 513 854 3031

**What processes are involved for a request to access data/document**

After evaluation of the request , up to two weeks data will be sent by e-mail.

**Comments**

Because our study was not about exact disease , ICD 10 code is undefined.