Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 acsitis 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

۹۱۳۷۹۱۳۳۱۶

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
Bita Abbasi
Street address
Radiology department, Imam Reza hospital, Next to Imam Reza square, Mashhad, Iran
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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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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
Bita Abbasi
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Radiology
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Person responsible for updating data

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Position
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Other areas of specialty/work

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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 scinces. 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.