

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of Percutaneous embolization with bleomycin sclerosing in patients with symptomatic liver hemangiomas

Protocol summary

Study aim

Study of the effect of Percutaneous embolization with bleomycin sclerosing in patients with symptomatic liver hemangiomas

Design

This study is a non-blinded clinical trial. The study population included all patients who referred to Imam Reza hospital of Kermanshah and whose liver ultrasound showed hepatic hemangioma. 19 eligible patients will be selected conveniently and randomly assigned to the intervention and control groups.

Settings and conduct

This study which will be conducted in Imam Reza hospital of Kermanshah is a non-blinded one. At the beginning of the study, the hemangioma profile in terms of the largest diameter and volume of measurement along with clinical signs are recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A giant hepatic hemangioma with clear margins; The number of platelets is more than 100,000; International Ratio Normalized less than 1/5 Exclusion criteria: Patients with severe ascites; Improper position of the hemangioma; Patients with hepatic or renal impairment

Intervention groups

In the intervention group, sclerotherapy (with 18 or 20 gage needles) will be performed with a mixture of 20 cc of IU 45 Bleomycin in 10 cc of distilled water and 10 cc of lipivitol. No intervention will be performed in the control group.

Main outcome variables

Ultrasound volume, the largest diameter of ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N154**

Registration date: **2020-11-06, 1399/08/16**

Registration timing: **prospective**

Last update: **2020-11-06, 1399/08/16**

Update count: **0**

Registration date

2020-11-06, 1399/08/16

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Percutaneous embolization with bleomycin sclerosing in patients with symptomatic liver hemangiomas

Public title

The effect of Percutaneous embolization in patients with symptomatic liver hemangiomas

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A giant hepatic hemangioma with clear margins The number of platelets is more than 100,000 International Ratio Normalized less than 1/5

Exclusion criteria:

Patients with severe ascites Improper position of the hemangioma Patients with hepatic or renal impairment

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 19

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table, patients are divided into two groups of 19. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

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 Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-03-02, 1398/12/12

Ethics committee reference number

ir.kums.rec.1399.226

Health conditions studied

1

Description of health condition studied

Liver symptomatic hemangioma

ICD-10 code

D18.0

ICD-10 code description

Haemangioma, any site

Primary outcomes

1

Description

Ultrasound volume

Timepoint

At the beginning of the study and 6 months after the end of the study

Method of measurement

Using the GE-Logic S6 ultrasound device

2

Description

Largest diameter of ultrasond

Timepoint

At the beginning of the study and 6 months after the end of the study

Method of measurement

Using the GE-Logic S6 ultrasound device

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, sclerotherapy (with 18 or 20 gage needles) will be performed with a mixture of 20 cc of IU 45 Bleomycin in 10 cc of distilled water and 10 cc of lipivdol

Category

Treatment - Other

2

Description

No intervention will be performed in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Loura Khanian

Street address

Emam Reza Hospital, Parastar Boulevard

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6715847141

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+98 83 3427 6306

Email

Loura.Khanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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fnajafi@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Loura Khanian

Position

Resident Radiology

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Gharib SALEHI

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

Resident Radiology

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

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

Documentation will be emailed within a 15-day timeframe

Comments