Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Percutanous sclerotherapy of symptomatic liver hemangioma with Bleomycin, a pilot study

Protocol summary

Summary

Objectives: Study of therapeutic outcome and complications of Percutanous sclerotherapy of symptomatic liver hemangioma with Bleomycin Design: Single center pilot study, 5 individuals sample size, Without blinding or randomization. Setting and conduct: In Patients with symptomatic liver hemangioma and with therapeutic indication undergo ultrasound guided sclerotherapy with Belomycin, Liver function tests and routine blood tests are done before the procedure and one week later. Triphasic CT-scan of liver is done 6 month after the procedure to evaluate therapeutic outcome. (4) Participants including major eligibility criteria: Patients with symptomatic liver hemangioma with therapeutic indication with confirmed diagnosis based on triphasic CT-scan or dynamic MRI. (5) Intervention: Percutanous sclerotherapy of symptomatic liver hemangioma with Bleomycin (6) Main outcome measures: Volume of liver hemangioma 6 month after sclerotherapy; Abdominal symptoms of patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021626599N1**
Registration date: **2016-03-31, 1395/01/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-03-31, 1395/01/12

Registrant information

Name

Hadi Rokni Yazdi

Name of organization / entity

Advanced Diagnostic and Interventional Radiology Research Center, Tehran University of Medical Scien

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Percutanous sclerotherapy of symptomatic liver hemangioma with Bleomycin, a pilot study

Public title

Sclerotherapy of liver hemangioma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with symptomatic liver hemangioma with therapeutic indication with confirmed diagnosis based on triphasic CT-scan or dynamic MRI. Exclusion criteria: Those patients that their abdominal complaints could be attributed to another cause, apart from liver hemangioma

Age

From **16 years** old to **80 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd Ghods Street Central Building of TUMS 6th Floor

City

Tehran

Postal code

Approval date

2015-09-22, 1394/06/31

Ethics committee reference number

IR.TUMS.REC.1394.1377

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

Volume of lesion

Timepoint

6 month after therapy

Method of measurement

Digital volumetry

Secondary outcomes

1

Description

Abdominal pain

Timepoint

one month and 6 month after procedure

Method of measurement

visual analog scale

Intervention groups

1

Description

Intervention group: Under local anesthectic and ultrasound guidance, needle is advanced into the liver hemangioma.Under flurouscopy contrast agent (Lipiodol) is injected to rule out communication of the lesion with portal vein or bile ducts. Then sclerotherapy agent (bleomycin 0.5IU/kg) is injected into the hemangioma tissue. The patient is kept under superviosion for 4 hours in the ward and then is discharged

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex, Medical Imaging Center

Full name of responsible person

Hadi Rokni Yazdi

Street address

Bagherkhan Street, Imam Khomeini Hospital Complex

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Akbari

Street address

Tehran, Keshavarz blvd, Ghods Street, Tehran University of Tehran Central Bulding, 6th floor

City

Tehran

Grant name

-

Grant code / Reference number

29429-98-02-94

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

Yes

Title of funding source

Vice Chancellor for Research, Tehran 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

Tehran university of Medical Sciences

Full name of responsible person

Hadi Rokni Yazdi

Position

Professor-MD

Other areas of specialty/work

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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