

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

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

Protocol summary

Summary

Objectives: Study of therapeutic outcome and complications of Percutaneous 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: Percutaneous 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

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Name of organization / entity

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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

Percutaneous 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 anesthetic and ultrasound guidance, needle is advanced into the liver hemangioma. Under fluoroscopy 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 supervision 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 Building, 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
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Person responsible for updating data

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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