

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Treatment of giant liver hemangioma by PVA particle embolization with or without bleomycin

Protocol summary

Study aim

This study aimed to evaluate the efficacy of the treatment of giant liver hemangioma with PVA embolization with and without bleomycin at one month, three months and six months.

Design

The control group will be treated with PVA particles for the treatment of giant liver hemangioma and the intervention group will be treated with PVA particles for the treatment of giant liver hemangioma with intravenous bleomycin injection. A randomized, double-blind, placebo-controlled clinical trial using the Cochran formula will be used to measure the minimum sample size (49), Phase 3.

Settings and conduct

Patients referred to the Shahid Mustafa Khomeini Center from 98 to 99 will be embolized with PVA particles with bleomycin and will be studied after obtaining written consent from patients with PVA particles with bleomycin. The right femoral artery will be guided by a hydrophilic guided approach with a Seldinger technique and a pigtail F 6 tail catheter will be used to perform abdominal aortography to evaluate the tumor arteries. We will then embolize the hemangioma feeder artery with PVA. Using 500-700 mm polyvinyl alcohol particles, according to the protocol, our IU30 bleomycin (2 vials 15 IU) will be used for smaller hemangiomas 10 cm in diameter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients with giant liver hemangioma have been diagnosed definitively by specialist physicians. 2. Patients with symptoms of hemangioma enlargement Exclusion criteria: 1- Patients' dissatisfaction Patients with INR> 1.5

Intervention groups

Control group: Treatment of patients with giant liver hemangioma by embolization with PVA particles
Intervention group: Treatment of patients with giant liver hemangioma by embolization with PVA particles with bleomycin

Main outcome variables

1- Size of liver hemangioma lesions 2. Level of liver enzymes 3. Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191105045343N1**

Registration date: **2019-12-16, 1398/09/25**

Registration timing: **prospective**

Last update: **2019-12-16, 1398/09/25**

Update count: **0**

Registration date

2019-12-16, 1398/09/25

Registrant information

Name

Mohammadreza Hosseini Siyanaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4422 3766

Email address

mohammadrhs1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Treatment of giant liver hemangioma by PVA particle embolization with or without bleomycin

Public title
Treatment of hemangioma by embolization

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with giant hemangioma diagnosed by the relevant specialist Patients with clinical signs of hemangioma enlargement
Exclusion criteria:
 No Patient's consent Patients with INR> 1.5

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: 49

Randomization (investigator's opinion)
Randomized

Randomization description
Given the small sample size, the random number table will be used and a completely random starting point will be selected on the table with closed eyes

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants, clinical caregivers, outcome assessors, data analysts, and safety and data monitoring committees had no information about treatment and intervention. It should be noted that the research participants were all aware of the presence of one study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Shahed University Ethics Committee
Street address
 Shahid Mostafa Khomeini Hospital, Italia street, Keshavarz Blvd,
City
 Tehran
Province
 Tehran
Postal code
 1454733965
Approval date
 2019-03-04, 1397/12/13
Ethics committee reference number
 IR.SHAHED.REC.1398.066

Health conditions studied

1

Description of health condition studied
Giant liver hemangioma

ICD-10 code
D18.0

ICD-10 code description
Hemangioma

Primary outcomes

1

Description
The size of liver hemangioma lesions

Timepoint
Before, immediately after the intervention, one, three, six months after the intervention

Method of measurement
Lesion size by ultrasound, CT scan, MRI

2

Description
liver enzymes

Timepoint
Before, immediately after the intervention, one, three, six months after the intervention

Method of measurement
Liver enzymes in the blood with a special kit

3

Description
The amount of pain

Timepoint
Before, immediately after the intervention, one, three, six months after the intervention

Method of measurement
Wong-baker criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with giant liver hemangioma are treated by embolization with PVA particles and intravenous injection of bleomycin with lipiodol.

Category

Treatment - Other

2

Description

Control group: Patients with giant liver hemangioma are treated by embolization with PVA particles. Intervention group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Dr.Mohammad reza Hosseini Siyanaki

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Shahid Mostafa Khomeini Hospital, Italia street,
Keshavarz Blvd,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr.Seyed Ali Golestanha

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Shahid Mostafa Khomeini Hospital, Italia
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Dr.Seyed Ali Golestanha

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Radiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mohammadreza Hosseini Siyanaki

Position

General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work
Radiology
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Person responsible for updating data

Contact
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Full name of responsible person
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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

Undecided - It is not yet known if there will be 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

Information and data can be transmitted completely transparently

When the data will become available and for how long

Access 6 months after the results are published

To whom data/document is available

Data is available to everyone

Under which criteria data/document could be used

Individuals are allowed to use data and results in their articles (with the reference cited) as well as to promote community health

From where data/document is obtainable

Email: mohammadrhs1373 @ Gmail.com

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

First, introduce the legal or legal person and use case results to make the next correspondence

Comments