

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Results of Ultrasonography-guided Intralesional Bleomycin Sclerotherapy for Treatment of Macrocystic Lymphangioma in Children and Comparison with traditional surgical methods

Protocol summary

Study aim

Results of Ultrasonography-guided Intralesional Bleomycin Sclerotherapy for Treatment of Macrocystic Lymphangioma in Children

Design

Two-group clinical trial, with parallel groups, without blinding, not randomized, on 20 patients. Excel software rand function was used for randomization.

Settings and conduct

This research is carried out in collaboration with professors of different wards of Tabriz Children's Hospital (surgery, ENT, oncology, radiology and pharmacist center). Sampling method is randomly selected from patients referred to surgical and ENT clinics in Tabriz Children Hospital.

Participants/Inclusion and exclusion criteria

Cysts in the lymphatic system in different parts of the body: entry Parental consent: entry Lymphangioma with small cysts: exit Previous surgery: exit

Intervention groups

The first group treats cysts with surgery The second group is treatment with Intralesional Sclerotherapy

Main outcome variables

Removal of lymphangioma with surgery or sclerotherapy

General information

Reason for update

Acronym

لنفانژیوم

IRCT registration information

IRCT registration number: **IRCT20150114020663N5**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **prospective**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Davoud Badebarin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2257

Email address

badebarind@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Results of Ultrasonography-guided Intralesional Bleomycin Sclerotherapy for Treatment of Macrocystic Lymphangioma in Children and Comparison with traditional surgical methods

Public title

Intralesional Bleomycin Sclerotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cysts in the lymphatic system in different parts of the body: entry Parental consent: entry

Exclusion criteria:

Lymphangioma with small cysts Previous surgery

Age

From **1 day** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Treatment of large lymphangiomas

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

no.44, Golsar Alley, Golbad Ave, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5165678691

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.391

Health conditions studied**1****Description of health condition studied**

Lymphangioma

ICD-10 code

D18.1

ICD-10 code description

Lymphangioma, any site

Primary outcomes**1****Description**

Recurrence of lymphangioma

Timepoint

6 month

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intralesional Bleomycin

Sclerotherapy: In patients in this group, injections are performed by one person and under ultrasound guide in the operating room and under general anesthesia. After a general examination of the cyst with examination and ultrasound in the operating room, first the fluid contents of the cysts are repeatedly emptied under the ultrasound guide by a 10 cc syringe and needle number 21. While the needle head is in the same place inside the cyst and the control is done by sono, the sclerosing substance is injected at the site. The required dose is 0.5 units per kilogram of body weight. The maximum amount of injection to prevent possible complications is 10 units of sclerosing material. The ratio of the amount of aspirated fluid to the volume of the sclerosing substance is 5: 1. For every 5 cc of aspirated fluid, one cc of fluid containing sclerosant is injected into the lesion. If a larger volume of sclerosing agent is needed, it is postponed to the second session, which is done 4 to 6 weeks later. For all cysts, this amount will be used in divided doses according to weight. Each vial of bleomycin contains 15 units of active ingredient that is diluted with normal saline to the desired volume and composition. 10 kg of 30 cc of aspiration from cyst V requires 5 units of 6 cc of bleomycin, for this patient a 15-unit vial with 18 cc of dissolved normal saline and 6 cc (containing 5 units of bleomycin). Blomycin is manufactured by Salius in India.

Category

Treatment - Other

2**Description**

Intervention group: Patients in this group undergo macrocystic resection and drainage by a single surgeon. After the operation, the monitored patients are evaluated for possible complications. At the end of six months, patients are evaluated for recurrence and late complications.

Category
Treatment - Surgery

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Chideren Hospital
Full name of responsible person
Davoud Badebarin
Street address
No.44, Golsar Alley. Golbad Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5165678691
Phone
+98 41 3325 2272
Email
badebarind@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohamad Samiei
Street address
Daneshgah Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5165788541
Phone
+98 41 3526 2257
Email
dbadebarin@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Davoud Badebarin
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric Surgery
Street address
No.44,Golsar Alley.Golbad Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5165678691
Phone
+98 41 3325 2272
Email
badebarind@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Davoud Badebarin
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
pediatric Surgery
Street address
No. 44. Golsar alley. Golbad Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5165678691
Phone
+98 41 3325 2272
Email
badebarind@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person

Dr. Davoud Badebarin

Position

Pediatric Surgery Sub-specialist.

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Department of Surgery, Imam Reza Hospital,
Daneshgah Street, Tabriz.

City

Tabriz

Province

East Azarbaijan

Postal code

5165678691

Phone

+98 41 3334 1317

Fax

Email

badebarind@tbzmed.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable