

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### comparision of efficacy of niosomal propranolo oint 0.1% versus atenolol oint 0.1% in the treatment of infantile hemangioma

#### Protocol summary

##### Summary

infantile hemangioma is one of the most common tumors. developed in 4-5% of infants. the therapeutic recommendation includes systemic or intralesional corticosteroids, cryotherapy, chemotherapy, lasers and surgery with a lot of side effects. patient with superficial hemangioma with no indications for systemic therapy from Afzalipoor hospital clinic after getting satisfaction will become in this study randomized divide in two groups A & B. group A will treat with topical propranolol 0.1% & B with topical atenolol 0.1% three times a day with thin layer of this ointment. this study is double blind and keeping investigator and patient blind to treatment. monthly visiting in one year and getting photograph in each visit. response to therapy measures with hemangioma severity table

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017100935611N1**

Registration date: **2017-10-09, 1396/07/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-09, 1396/07/17

##### Registrant information

##### Name

marjan tavakoli nejad

##### Name of organization / entity

kerman medical university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 8237

##### Email address

m.tavakoli@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

investigator

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparision of efficacy of niosomal propranolol oint 0.1% versus atenolol oint 0.1% in the treatment of infantile hemangioma

##### Public title

comparision of efficacy of niosomal propranolol oint 0.1% versus atenolol oint 0.1% in the treatment of infantile hemangioma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria : age less than 12 month, definite diagnose of superficial hemangioma  
exclusion criteria : sinus bradycardia, atrioventricular block, asthma, bronchitis, pneumonitis, maternal cardiac disease or other systemic disorder, allergy to beta blockers, history of treatment with beta blockers, systemic corticosteroids, interferon, cyclophosphamide and vincristine

##### Age

From **10 days** old to **1 year** old

**Gender**

Both

**Phase**

1

**Groups that have been masked***No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

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

Double 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 kerman medical university

**Street address**kerman- haftbagh road-kerman university of medical  
science\postal code:76169-13555  
\phone:034-31325700**City**

kerman

**Postal code**

76169-13555

**Approval date**

2017-08-16, 1396/05/25

**Ethics committee reference number**

IR.KMU.REC.1396.1179

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

Hemangioma

**ICD-10 code**

D18.0

**ICD-10 code description**

Haemangioma, any site

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

size of lesion

**Timepoint**

monthly

**Method of measurement**

ruler

**Secondary outcomes****1****Description**

age

**Timepoint**

before starting study

**Method of measurement**

birth certification

**2****Description**

gender

**Timepoint**

before starting study

**Method of measurement**

asking

**3****Description**

place of lesion

**Timepoint**

before starting study

**Method of measurement**

looking

**4****Description**

time of beginning

**Timepoint**

before starting study

**Method of measurement**

asking

**5****Description**

vital signe

**Timepoint**

monthly

**Method of measurement**

examing

**6****Description**

lab test

**Timepoint**

first-second and third month

**Method of measurement**

laboratory

## Intervention groups

### 1

#### Description

patient in group A treat with niosomal propranolol oint 0.1% three times aday applying thin layer of this ointment.and coming to clinic every month for one year and taking photo every month

#### Category

Treatment - Drugs

### 2

#### Description

patient in group B treat with niosomal atenolol oint 0.1% three times a day applying thin layer of this ointment and coming to clinic every month for one year and taking photo every month

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

clinic of afzalipour hospital of krman

##### Full name of responsible person

dermatology resident

##### Street address

kerman-imam khomeyni highway

##### City

kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

vice chancellor for research of kerman university of medical scieces

##### Full name of responsible person

Dr.Abbas pardakthy

##### Street address

shafas street-kerman

##### City

kerman

#### Grant name

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#### Grant code / Reference number

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

Yes

#### Title of funding source

vice chancellor for research of kerman university of medical scieces

#### 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

kerman medical university

##### Full name of responsible person

Dr.maryam khalili

##### Position

dermatologist

##### Other areas of specialty/work

##### Street address

kerman afzalipoor hospital

##### City

kerman

##### Postal code

76169-13555

##### Phone

+98 343322225060

##### Fax

+98 33222763

##### Email

m-khalili@kmu.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

kerman medical university

##### Full name of responsible person

Dr.saeedeh farajzadeh

##### Position

professor

##### Other areas of specialty/work

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safaderm@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

**Name of organization / entity**

kerman medical university

**Full name of responsible person**

tavakoli nejad kermani-marjan

**Position**

dermatology resident

**Other areas of specialty/work****Street address**

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**Email**

marjanta\_66@yahoo.com

**Web page address****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*