

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparative evaluation of clinical efficacy of intra- leisonal TriamHexal with and without Anti-VEGF(Bevacizumab) in treatment of keloidal leisons

#### Protocol summary

##### Study aim

Comparison of clinical efficacy of intra- leisonal TriamHexal with and without Anti-VEGF(Bevacizumab) in treatment of keloid lesions

##### Design

A simple randomized clinical trial (phase 3) (using random allocation software) with control group (parallel groups) and double blinded on 40 patients with keloid lesions enrolled between 2019-2020.

##### Settings and conduct

This study is performed on patients with keloidal lesions referred to dermatology clinics of Isfahan University of Medical Sciences. A keloidal lesion in each individual is selected randomly. One group will receive intralesional Triamhexal injection and the other group (intervention group) will receive intralesional Avastin in addition to Triamhexal injection. The patients will be evaluated for outcomes and side effects. Patient and service provider are unaware of the type of medication given to the patient (double blinded).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 1 keloidal lesion in the trunk and extremities; age 18 to 70 years old; Informed consent to participate in the study. Exclusion criteria: pregnancy; breastfeeding; history of cardiovascular diseases; unwillingness to continue treatment; not following up; patients with severe side effects; patients who have had previous keloid therapy; infection at the injection site.

##### Intervention groups

Intervention group: intralesional administration of 20 mg/dl TriamHexal plus 2/5 mg/dl intralesional Avastin (/1 cc to 1cc from vial of Avastin). Control group: administration of 20 mg/dl intralesional TriamHexal.

##### Main outcome variables

Improvement rate according to physician's point of view; patient satisfaction score; treatment side effects

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131119015455N5**

Registration date: **2020-02-10, 1398/11/21**

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

Last update: **2020-02-10, 1398/11/21**

Update count: **0**

##### Registration date

2020-02-10, 1398/11/21

##### Registrant information

##### Name

Bahareh Abtahi-Naeini

##### Name of organization / entity

Skin Diseases and leishmaniasis research Center, Isfahan University of Medical Sciences, Isfahan, Ir

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1264 2901

##### Email address

bahareh.abtahi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-22, 1398/07/30

##### Expected recruitment end date

2020-04-18, 1399/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparative evaluation of clinical efficacy of intralesional TriamHexal with and without Anti-VEGF(Bevacizumab) in treatment of keloidal lesions

## Public title

Efficacy of TriamHexal with and without Anti-VEGF(Bevacizumab) in treatment of keloidal lesions

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

At least 1 keloidal lesion in the trunk and extremities Age 18 to 70 years old Informed consent to participate in the study

### Exclusion criteria:

Pregnancy Breastfeeding History of cardiovascular diseases Unwillingness to continue treatment Not following up Patients with severe side effects Patients who have had previous keloid therapy Infection at the injection site

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A keloidal lesion in each individual is selected randomly using simple randomization by Random Allocation Software. One group will receive intralesional Triamhexal injection and the other group (intervention group) will receive intralesional Avastin in addition to Triamhexal injection.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This is a double blinded study in which the patient and service provider are unaware of the type of medication given to the patient.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Isfahan University of Medical Sciences

#### Street address

Research and Technology Deputy of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Approval date

2019-06-26, 1398/04/05

#### Ethics committee reference number

IR.MUI.MED.REC.1398.163

## Health conditions studied

## 1

### Description of health condition studied

Keloidal lesions

### ICD-10 code

L91.0

### ICD-10 code description

Hypertrophic scar

## Primary outcomes

## 1

### Description

Improvement rate according to physician's point of view

### Timepoint

4, 8, 12 weeks and then 3 months after intervention

### Method of measurement

Vancouver score and photography assessment by two blinded dermatologists.

## 2

### Description

Patient satisfaction score

### Timepoint

3 months and 6 months after intervention

### Method of measurement

Visual Analogue Scale

## Secondary outcomes

## 1

### Description

Treatment side effects

### Timepoint

2 days after of each injection

### Method of measurement

After the patient is instructed about possible side effects,

the patient will be consulted by telephone to refer to the physician in case of severe side effects.

## Intervention groups

### 1

#### Description

Intervention group: Administration of 20 mg/dl intralesional TriamHexal (made in Germany) at weeks 0, 4, and 8 and administration of 2/5 mg/dl intralesional Avastin (made in Switzerland) (/1 cc to 1cc from vial of Avastin) at weeks 2 and 6.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Administration of 20 mg/dl intralesional TriamHexal (made in Germany) at weeks 0, 4, and 8

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Skin Diseases and Leishmaniasis Research Center

##### Full name of responsible person

Dr. Zabihollah Shahmordi

##### Street address

Hazrat Sedighe Tahereh Complex, Khorram Ave,  
Isfahan

##### City

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##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3335 9090

##### Email

sdLrc@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

##### Street address

Research and Technology Deputy of Medical  
Sciences, Hezar Jerib Avenue, Isfahan

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##### Postal code

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##### Phone

+98 31 3792 3061

##### Email

research@mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Bahareh Abtahi

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dermatology

##### Street address

Skin Diseases and Leishmaniasis Research Center,  
Hazrat Sedighe Tahereh Complex, Khorram Ave,  
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##### Postal code

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bahareh.abtahi@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Zabihollah Shahmordi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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Dr. Bahareh Abtahi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Phone**

+98 31 3335 9090

**Email**

bahareh.abtahi@med.mui.ac.ir

**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**

Yes - There is 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**

Primary outcome data can be shared, if our committee approves.

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

People working in academic institutions

**Under which criteria data/document could be used**

Descriptive analysis is allowed to report on data

**From where data/document is obtainable**

Bahareh Abtahi Skin Diseases and Leishmaniasis  
Research Center, Isfahan, Iran Email:  
bahareh.abtahi@med.mui.ac.ir

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

The request is discussed in the Center Committee and after approval, the data is submitted to the applicant over a period of approximately one month.

**Comments**