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 intra-leisonal TriamHexal with and without Anti-VEGF(Bevacizumab) in treatment of keloidal leisons

Public title
Efficacy of TriamHexal with and without Anti-VEGF(Bevacizumab) in treatment of keloidal leisons

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
Isfehan

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
Vancuver 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
Isfahan
Province
Isfehan
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
City
Isfahan
Province
Isfehan
Postal code
8174673461
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, Isfahan
City
Isfahan
Province
Isfehan
Postal code
7346181746
Phone
+98 31 3335 9090
Email
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
Street address
Hazrat Sedighe Tahereh Complex, Khorram Ave, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3335 9090
Email
sdlrc@mui.ac.ir

Person responsible for updating data

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, Isfahan
City
Isfahan
Province
Isfehan
Postal code
7346181746
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