Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of topical and oral isotretinoin in treatment of facial papules in the frontal fibrosing alopecia patients

Protocol summary

Study aim

Comparison of the effect of topical and oral isotretinoin in the treatment of facial papules in patients with frontal fibrosing alopecia

Design

This open-label clinical trial will be performed in a phase III study of 22 patients in 2 groups of 11 patients. Patients will be randomly divided into two groups using random allocation software. The first group will be treated with oral and the second group will be treated with topical isotretinoin.

Settings and conduct

Patients referred to the dermatology clinic of Al-Zahra Hospital and Sedigheh Tahereh that meeting inclusion criteria will be randomly divided into two groups. Before starting treatment, patients fill out the patient information form and standard photography is performed on each patient. Both groups will be tested according to the protocol before and during treatment. Assessment of improvement score indices, patient satisfaction, and treatment side effects will be performed monthly in both groups for up to 3 months after initiation of treatment. This study will be done as an open-label clinical trial.

Participants/Inclusion and exclusion criteria

Patients with frontal fibrosing alopecia that have facial papule will be included. Patients with the above conditions that have contraindications to the drug that uses in the study or are taking drugs that interact with isotretinoin will be excluded.

Intervention groups

The first group will be received oral isotretinoin and the second group will be received topical isotretinoin

Main outcome variables

Global Aesthetic Improvement Scale Side effects of treatment Patient satisfaction of the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200314046767N1**
Registration date: **2020-03-25, 1399/01/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-25, 1399/01/06**
Update count: **0**

Registration date

2020-03-25, 1399/01/06

Registrant information

Name

Mahsa Bahraminejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3673 0739

Email address

m.bahraminejad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-19, 1398/09/28

Expected recruitment end date

2020-06-17, 1399/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of topical and oral isotretinoin in treatment of facial papules in the frontal fibrosing alopecia patients

Public title
Comparison of the effect of topical and oral isotretinoin in treatment of frontal fibrosing alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with facial papules diagnosed on the basis of clinicopathological evidence. (Evidence of inflammation and fibrosis seen in papules).
Exclusion criteria:
Pregnant or intended to be pregnant patients Lactating patients Patients with a history of allergy to retinoid compounds Known liver or kidney disease or abnormalities in related blood tests (leukopenia, moderate to severe hypercholesterolemia, hypertriglyceridemia, hypothyroidism, liver and kidney dysfunction) Patients with a history of pseudotumor cerebri Patients with a history of suicidal ideation Patients taking drugs that interact with isotretinoin
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who met the inclusion criteria will randomly divided into two groups using random allocation software, this software creates a random sequence by blocking method. Each patient participating in the study will receive a unique code, and the person performing the randomization with the software will not be informed of any further actions and interventions. After assigning the code the patients will be divided into two groups then the first group received oral form and the second group received topical form of isotretinoin.
Blinding (investigator's opinion)
Not 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 Isfahan University of Medical Sciences
Street address
Soffeh Blvd
City
Isfahan
Province
Isfehan
Postal code
8174675731
Approval date
2019-12-18, 1398/09/27
Ethics committee reference number
IR.MUI.MED.REC.1398.473

Health conditions studied

1

Description of health condition studied
Frontal fibrosing alopecia
ICD-10 code
L66.8
ICD-10 code description
Other cicatricial alopecia

Primary outcomes

1

Description
Recovery score based on Global Aesthetic Improvement Scale
Timepoint
Before the start of the study and 1 , 2 , 3 months after the start of treatment
Method of measurement
Grading the scale of global aesthetics based on observation

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will receive 20 mg oral isotretinoin daily in the form of 20 mg capsules(made by pharmaceutical Zahravi Co.) with lunch meal for 3 months.
Category
Treatment - Drugs

2

Description
The second intervention group will receive topical isotretinoin in the form of 0.05% gels(made by pharmaceutical Raha Co.) in the amount of o.5 fingertip

every night for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mahsa bahraminejad

Street address

Soffe Blvd

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Hezarjarib Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.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

Mahsa Bahraminejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Soffe Blvd

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

m.bahraminejad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahsa Bahraminejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Soffe Blvd

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

m.bahraminejad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
Mahsa Bahraminejad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Soffe Blvd
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3668 5555
Email
m.bahraminejad@yahoo.com

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
The primary outcome data will be shared
When the data will become available and for how long
En Start the access period is 6 months after publishing the results
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
The request can be made by e-mail to the corresponding author
From where data/document is obtainable
It can be done by e-mail to m.bahraminejad@yahoo.com
What processes are involved for a request to access data/document
Once the applicant has provided details of their ongoing project within one month from the time of application data will be available.
Comments