Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of combination therapy by oral isotretinoin, local clobetasol, and tacrolimus in comparison to local clobetasol, and tacrolimus on patients with Frontal Fibrosing Alopecia

Protocol summary

Summary

In this single-blind randomised clinical trial 34 patients with FFA will be divided into 2 same group. Inclusion criteria are patients with clinicopathologically proven FFA, older than 18 years and exclusion criteria are 1. pregnancy 2. inability to participate or follow the trial 3. severe hypertriglyceridemia 4. liver enzyme disturbance 5. consumption of immunosuppressant or another kind of LLP or FFA therapies during recent 3 months. in one group combination therapy by oral isotretinoin, local clobetasol, and tacrolimus will be prescribed and in other group local clobetasol, and tacrolimus.before trial entrance and then in 2, 4 and 6 months after the results for both groups will be compared by Frontal Fibrosing Alopecia Severity Index (FFASI) and Fotofinder for hair diameters or density, itching and hiar loss.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091736173N1**
Registration date: **2017-10-25, 1396/08/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-25, 1396/08/03

Registrant information

Name

Hamidreza Mahmoudi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of combination therapy by oral isotretinoin, local clobetasol, and tacrolimus in comparison to local clobetasol, and tacrolimus on patients with Frontal Fibrosing Alopecia

Public title

Study of combination therapy by oral isotretinoin, local clobetasol, and tacrolimus in comparison to local clobetasol, and tacrolimus on patients with Frontal Fibrosing Alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with clinicopathologically proven FFA, older than 18 years Exclusion criteria: 1. pregnancy 2. inability to participate or follow the trial 3. severe hypertriglyceridemia 4. liver enzyme disturbance 5. consumption of immunosuppressant or another kind of

LLP or FFA therapies during recent 3 months

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

1

Registry name
000000

Secondary trial Id
000000

Registration date
2017-11-22, 1396/09/01

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences, School of Medicine

Street address
Tehran, Enghelab Avenue. Tehran University of Medical Siences, school of medicine

City
Tehran

Postal code

Approval date
2017-10-15, 1396/07/23

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3707

Health conditions studied

1

Description of health condition studied
Frontal Fibrosing Alopecia

ICD-10 code
L66.1

ICD-10 code description
Lichen planopilaris

Primary outcomes

1

Description
Frontal Fibrosing Alopecia Severity Index (FFASI)

Timepoint
before trial and in 2, 4, and 6 months later

Method of measurement
Questionaire

2

Description
hair amount and density

Timepoint
before trial and in 2, 4, and 6 months later

Method of measurement
Fotofinder

3

Description
clinical presentations (itching and irritation)

Timepoint
before trial and in 2, 4, and 6 months later

Method of measurement
Patient asking

Secondary outcomes

1

Description
Perifollicular scaling

Timepoint
before trial and in 2, 4, and 6 months later

Method of measurement
Trichoscope

2

Description
Perifulicular erythema

Timepoint
before trial and in 2, 4, and 6 months later

Method of measurement
Trichoscope

Intervention groups

1

Description
in the first group the first 2 weeks of intervention includes local daily clobetasol for 5 days then local tacrolimus daily for 2 days, at the end of second week the patient will apply local daily tacrolimus for 5 days and local daily clobetasol for 2 days. in the second group

the same intervention will be done while oral isotretinoin 20 mg every other day for one month then daily for second month will be ordered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Hamidreza Mahmoudi

Street address

Tehran Province, Tehran, District 12, Vahdat-e-Islami St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Mahmoudi

Street address

Tehran Province, Tehran, District 12, Vahdat-e-Islami St

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Amini

Position

Dermatology Resident

Other areas of specialty/work

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Position

Dermatologist, Assistant Professor of Dermatology

Other areas of specialty/work

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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