

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 hair 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)

##### Phone

+98 55630174021

##### Email address

mahmoudi\_h@sina.tums.ac.ir

##### 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 Sciences, 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

Questionnaire

### 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

Perifollicular 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****Street address**

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

**City**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5563 0223

**Fax**

+98 55620300

**Email**

Flipopart@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Hamidreza Mahmoudi

**Position**

Dermatologist, Assistant Professor of Dermatology

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

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

**City**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5563 0223

**Fax**

+98 55620300

**Email**

mahmoudi\_h@sina.tums.ac.ir

**Web page address****Person responsible for updating data****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****Street address**

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

**City**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5563 0223

**Fax**  
+98 55620300  
**Email**  
Flipopart@gmail.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*