# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

05 Jun 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**

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**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

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## Person responsible for scientific inquiries

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**Latest degree**

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## Person responsible for updating data

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**Latest degree**
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## 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**