

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical trial of Comparison of the efficacy and safety of finasteride and hydroxy chloroquine on frontal fibrosing severity index in patients with frontal fibrosing alopecia

Protocol summary

Study aim

1. Finding appropriate and uncomplicated treatment in patients with frontal fibrosing alopecia
2. Comparison of the efficacy and safety of finasteride and hydroxy chloroquine for treatment of frontal fibrosing alopecia

Design

A clinical trial with phase2 ,randomized. paralell groups is performed on 30 patients.

Settings and conduct

This study is a randomized clinical trial performed in the dermatology clinics and teaching hospitals affiliated to Esfahan university of medical science. Sampling is performed among patients referred to dermoscopy clinic affiliated to the Esfahan university of medical science and if they have the conditions to enter and leave the study are considered as an sample. And then randomly divided into two treatment groups in this study. Before starting treatment, patients are evaluated in 3 ways: 1. Disease activity index 2. Photography 3. Trichoscopy After 2, 4 and 6 months from the start of treatment, patients are re-evaluated for the above.

Participants/Inclusion and exclusion criteria

New cases with FFA who have not yet received any medication; patients who have previously received systemic therapy and have not received systemic medication for at least the last three months and according to clinical and dermoscopic criteria, their disease is active; patients treated with topical medication and according to clinical and dermoscopic criteria, their disease is active

Intervention groups

1-Finasteride (2.5mg/day orally)will be administered in one group(15 patients) and for 6 months. 2-Hydroxy choloroquine (400mg/day orally)will be administered in one group(15 patients) and for 6 months.

Main outcome variables

1. Frontal fibrosing alopecia severity index 2.

Standardized global photography 3.Tricoscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210513051276N1**

Registration date: **2021-06-03, 1400/03/13**

Registration timing: **prospective**

Last update: **2021-06-03, 1400/03/13**

Update count: **0**

Registration date

2021-06-03, 1400/03/13

Registrant information

Name

maryam farokhshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3626 3129

Email address

farokhshahimaryam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Comparison of the efficacy and safety of finasteride and hydroxy chloroquine on frontal fibrosing severity index in patients with frontal fibrosing alopecia

Public title

The effect of finasteride and hydroxy chloroquine on frontal fibrosing alopecia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

New cases with FFA who have not yet received any medication. Patients who have previously received systemic therapy and have not received systemic medication for at least the last three months and according to clinical and dermoscopic criteria, their disease is active. Patients treated with topical medication and according to clinical and dermoscopic criteria, their disease is active

Exclusion criteria:

Pregnancy or lactation History of hypersensitivity due to hydroxychloroquine or finasteride Patients with severe blood dyscrasia and liver dysfunction Patients with retinopathy Personal history or family history of breast cancer

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked*No information***Sample size**

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is performed among patients referred to dermoscopy clinic affiliated to the esfahan university of medical science and if they have the conditions to enter and leave the study are considered as an sample. Random function of Excel software based on patient file number will be used for randomization. Patients with frontal fibrosis alopecia are entered in Excel according to the file number and are divided into two groups of finasteride and hydroxychloroquine based on the random button. Once the file numbers are entered in Excel, then select the repeating each number option and select 15 repeating the sequence. In this way, 30 will be produced. Then, from the data analysis command, the random number is selected. It is clear that the repetition of each number occurs once in each group, for a total of two groups of 15 people.

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 Esfahan University of Medical Sciences

Street address

AL Zahra Hospital, Dermatology Department, Sofeh Street, Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

8174645731

Approval date

2021-03-19, 1399/12/29

Ethics committee reference number

IR.MUI.MED.REC.1399.1194

Health conditions studied**1****Description of health condition studied**

Frontal fibrosing alopecia

ICD-10 code

L66.9

ICD-10 code description

Cicatricial alopecia, unspecified

Primary outcomes**1****Description**

Frontal fibrosing alopecia severity index

Timepoint

Before and after intervention

Method of measurement

Checklist

2**Description**

Standardized global photography

Timepoint

Before and after intervention

Method of measurement

Based on scoring by two dermatologist

3

Description

Tricoscopy

Timepoint

Before and after intervention

Method of measurement

Based on scoring by two dermatologist

Secondary outcomes

empty

Intervention groups

1

Description

A group of 15 patients are treated with finasteride tablets of 2.5 mg daily for 6 months.

Category

Treatment - Drugs

2

Description

Intervention group: A group of 15 patients treated with hydroxychloroquine 400 mg daily for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Maryam Farokhshahi

Street address

Alzahra Hospital, Dermatology Department, Sofeh Street, Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

8174645731

Phone

+98 31 3669 5414

Email

farokhshahimaryam@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

دکتر شقایق حق جو جوانمرد

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 7898

Fax

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address

<https://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

Maryam Farokhshahi

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Person responsible for updating data

Contact

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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

Dissemination of data that has nothing to do with the personality and identity of the participants in the study and are merely the consequences of the study.

When the data will become available and for how long

Start the access period after the article is published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions, after their authentication by the relevant university.

Under which criteria data/document could be used

The data can only be used for research and writing review articles.

From where data/document is obtainable

The author will be available via the email and university phone number mentioned in the article.

What processes are involved for a request to access data/document

Access to the data is granted if it is found that the data has been requested for non-industrial and non-commercial use.

Comments