Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative of Betamethasone pulse, Methotrexate pulse and Betamethasone Combination using Methotrexate pulse Therapy in Treatment of Severe Alopecia Areata

Protocol summary

Study aim

Comparison of betamethasone pulse, methotrexate pulse and pulse betamethasone combination with methotrexate in the treatment of severe alopecia areata.

Design

This clinical trial will be carried out in a double-blind randomized trial in Phase III studies consist of 36 patients in 3 groups .according to the random numbers table. the sample size was considered in each group of 12 patients Patients, the first group is treated with betamethasone pulse, the second group is treated with methotrexate pulse and the third group is treated with pulse methotrexate and betamethasone.

Settings and conduct

Patients referred to the Dermatology Clinic of Al Zahra Hospital and Sedigheh Tahereh, with the criteria for entering the study, are numbered and the numbers are randomly divided into three groups. In all three groups, the necessary tests will be performed prior to the start of the treatment, and During the study according to the protocol. After 6 months of treatment, patients were evaluated for the response rate and relapse for another three months by using photographic and VAS changes in patients' recovery. This is a double-blind clinical trial in which patients, researchers, evaluators, and analysts of any of the treatment groups will not be informed.

Participants/Inclusion and exclusion criteria

Patients with severe alopecia areata and resistant to treatment will be included in the study. If patients with the above conditions have contraindications for use of the drugs or Within a month prior to the study they had received systemic treatment Will not enter the study.

Intervention groups

The first group treated with betamethasone. The second group receives methotrexate. The third group receives methotrexate plus betamethasone.

Main outcome variables

Score of photographic scores; VAS score; percentage of the extent of the disease at the start of treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181226042136N1**
Registration date: **2019-01-15, 1397/10/25**
Registration timing: **retrospective**

Last update: **2019-01-15, 1397/10/25**
Update count: **0**

Registration date

2019-01-15, 1397/10/25

Registrant information

Name

Zakiye Ganjei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2087

Email address

z.ganjei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2017-07-23, 1396/05/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2018-12-22, 1397/10/01

Scientific title

Comparative of Betamethasone pulse, Methotrexate pulse and Betamethasone Combination using Methotrexate pulse Therapy in Treatment of Severe Alopecia Areata

Public title

Comparison of Betamethasone and Methotrexate efficacy in the Treatment of Alopecia Areata

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The scalp involvement rate more than 50% The disease is resistant to systemic and topical combination therapy The patient is satisfied with the study

Exclusion criteria:

Pregnancy or Breastfeeding Hb less than 9mg/dl Leukocyte less than 4000 Platelet less than 100000 Potassium is less than 3.5 Liver enzymes 2 times more than the reference limit ESR above reference limit Positive Stool Test for Strongyloides stercoralis Positive tests for viral hepatitis Use of any systemic drug a month before the start of the study There is a contraindication for betamethasone (diabetes, high blood pressure, drug allergy, active infection, recent surgery history, osteoporosis, stomach ulcer and psychosis, or depression) Sensitivity to methotrexate

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Actual sample size reached: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients whose entry criteria apply to them are numbered and the number of Habs based on the random numbers table is divided into three groups. Patients in the first group were treated with betamethasone pulse, the second group was treated with methotrexate pulse and the third group treated pulse combinations Methotrexate and Betamethasone

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, researchers and, evaluators will not be aware of the treatment groups, Medications are given to patients without a name and specification. Information will be provided to surveyors in the form of questionnaires delivered to the evaluators. The data is given for analysis as encoded and unnamed groups and profiles to the information analyzer.

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

2017-06-22, 1396/04/01

Ethics committee reference number

IR.MUI.MED.REC.1397.146

Health conditions studied

1

Description of health condition studied

Alopecia Areata

ICD-10 code

L63

ICD-10 code description

Alopecia areata

Primary outcomes

1

Description

Photographic Scoring for patients with Alopecia Areata

Timepoint

Before the start of the study and 3 , 6, 9 months after the start of treatment

Method of measurement

Photographic Scoring

2

Description

Visual Analogue Scale Score in patient with Alopecia Areata

Timepoint

Before the start of the study and 3 , 6, 9 months after the start of treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The first group will be treated with 3 mg betamethasone per oral in the form of 0.5 mg tablets (made by Iran Hormones Co.) and with a dose of 1 mg for breakfast, lunch, and dinner on a specified day, weekly, for 6 months.

Category

Treatment - Drugs

2

Description

Intervention group 2: The second group will be treated with 15 mg methotrexate per oral in the form of 2.5 mg tablets (Ebetrex made by Pfizer Co) and with a dose of 5 mg for breakfast, lunch and dinner, on a specified day, weekly, for 6 months.

Category

Treatment - Drugs

3

Description

Intervention group 3: The third group will be treated with 15 mg methotrexate per oral in the form of 2.5 mg tablets (Ebetrex made by Pfizer Co) and with a dose of 5 mg for breakfast, lunch and dinner on a specified day(Friday) plus 3 mg betamethasone PO in the form of 0.5 mg tablets (made by Iran Hormones Co.) and with a dose of 1 mg for breakfast, lunch and dinner, on another specified day(Saturday), weekly, for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Zakiye Ganjei

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Isfahan

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8174673461

Phone

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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

Zakiye Ganjei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work
Dermatology
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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
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 z.ganjei@gmail.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