

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the effect of mesotherapy with a combination of biotin and dexpanthenol in the treatment of androgenetic alopecia in women

Protocol summary

Study aim

Determining the effectiveness of mesotherapy with a combination of biotin and dexpanthol in women with androgenetic alopecia

Design

This study is a controlled clinical trial with parallel, double-blind, randomized, phase 3 in two groups on 72 patients. Random Allocation software was used for randomization.

Settings and conduct

This study is performed as a clinical trial in Al-Zahra Educational and Medical Center of Isfahan. Patients were randomly divided into two groups: the first group used mesotherapy with biotin and dexpanthenol and the second group used normal saline as a placebo. Evaluation of response to treatment in patients is performed at 18 weeks from the start of treatment (2 weeks after the last microneedling). In order to evaluate the treatment, there are two methods of photography and the patient's own opinion about the outcome of the treatment.

Participants/Inclusion and exclusion criteria

The target population of the present study are women aged 18 to 45 years with female pattern hair loss, the diagnosis of which has already been confirmed by a dermatologist based on history and physical examination. Patients with inclusion criteria will be included in the study and patients who have exclusion criteria will be excluded from the study.

Intervention groups

In the first group, patients undergoing mesotherapy with microneedling with a solution of 20 mg of biotin + 500 mg of dexpanthenol per month plus topical minoxidil 2% twice a day. In the second group, normal saline is used as a placebo and mesotherapy is performed by microneedling with normal normal saline. Also, patients receive topical minoxidil 2% twice a day.

Main outcome variables

Appearance based on photography, intensity based on

Ludwig grading, number of hairs plucked in hair pulling test, patient opinion on density, thickness, hair loss and hair quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181226042136N2**

Registration date: **2020-08-31, 1399/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-31, 1399/06/10**

Update count: **0**

Registration date

2020-08-31, 1399/06/10

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

2020-04-19, 1399/01/31

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of mesotherapy with a combination of biotin and dexpanthenol in the treatment of androgenetic alopecia in women

Public title
Evaluation of the effect of mesotherapy in the treatment of hair loss

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having a female pattern hair loss Do not use other hair loss treatments at the time of enrollment Do not use temporary and permanent hair dye and curl or straighten hair Do not use aspirin, warfarin, steroids, oral retinoids, hormones or cytotoxic drugs Absence of pregnancy and lactation Absence of high androgenic blood levels, irregular periods, acne and hirsutism, thromboembolic events, low ferritin blood levels and impaired TSH
Exclusion criteria:
Allergic reaction to the drug used Failure to complete the course of treatment and failure to refer for follow-up, which results in a drawing on the case file or the patient Local reactions such as abscesses, inflammation and cellulite at the injection site The patient's decision not to participate in the study

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are placed in random groups using Random Allocation software and Block Randomization method and all patients are unaware of their grouping.

Blinding (investigator's opinion)
Double blinded

Blinding description
First, patients are randomly divided into two groups. 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

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
Hezar-Jerib
City
Isfahan
Province
Isfahan
Postal code
81746 73461

Approval date
2020-05-26, 1399/03/06

Ethics committee reference number
IR.MUI.MED.REC.1399.181

Health conditions studied

1

Description of health condition studied
female androgenetic alopecia

ICD-10 code
L64

ICD-10 code description
Androgenic alopecia

Primary outcomes

1

Description
Appearance based on photography

Timepoint
Photographs will be taken first before the start of treatment and finally two weeks after the microneedling sessions

Method of measurement
By a dermatologist

2

Description
Intensity based on Ludwig Griding

Timepoint
It is performed before treatment and at 18 weeks by a dermatologist who is unaware of the patient's grouping

Method of measurement

By a dermatologist

3

Description

Number of hairs plucked in the hair pulling test

Timepoint

The number of hairs removed before treatment and after 18 weeks is counted and recorded.

Method of measurement

In the hair pull test, about 20-30 hairs in the vortex area between the thumb and the other 4 fingers are gently pulled and pulled vertically.

4

Description

Patient opinion about density, thickness, hair loss and quality

Timepoint

before and after the treatment

Method of measurement

In the self-assessment of the patient, the result of the treatment is asked about increasing hair density, increasing hair thickness, hair loss rate and hair quality (color and transparency). Answers are considered as worsening 1-, without changing 0 and improving 1

Secondary outcomes

1

Description

Complications

Timepoint

In each session

Method of measurement

Complications of treatment in each session, including headache, cramping, itching, ecchymosis, puffy eyes, increased hair growth in other parts of the body and changes in menstrual patterns, patients are asked and recorded.

Intervention groups

1

Description

Intervention group: In the case group, patients undergoing mesotherapy with microneedling with a solution of 20 mg of biotin + 500 mg of dexpanthenol per month plus topical minoxidil 2% twice a day. The duration of the treatment period is 16 weeks. The volume of the substance used in each injection session is 3 cc. After disinfecting the vortex, first microneedling will be done with a 12-needle microneedle needle with a depth of 1.5 cm. Then, the desired materials in each group will be applied on the microneedle site and the patient's head will be bandaged.

Category

Treatment - Drugs

2

Description

Control group: In the control group, normal saline is used as a placebo and patients also receive 2% topical minoxidil twice a day in addition to mesotherapy with normal saline microneedling. The duration of the treatment period is 16 weeks. The volume of the substance used in each injection session is 3 cc. After disinfecting the vortex, first microneedling will be done with a 12-needle microneedle needle with a depth of 1.5 cm. Then, the desired materials in each group will be applied on the microneedle site and the patient's head will be bandaged.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Educational and Medical Center

Full name of responsible person

Zakiye Ganjei

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sofeh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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

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Full name of responsible person

Zakiye Ganjei

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not 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