Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 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 dexpantol 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

Isfehan

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
Street address
sofeh Blvd
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 1668 5555
Email
z.genjei@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zakiye Ganjei
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 7270
Email
z.ganjei@gmail.com
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
Street address
hezar jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 7270
Email
z.ganjei@gmail.com

Person responsible for scientific 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
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 7270
Email
z.ganjei@gmail.com

Person responsible for updating data

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
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 7270
Email
z.ganjei@gmail.com

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