

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of herbal product based on henna (low sonia inermis), Myrtus communis and mastica(pistacia lentiscus) on men's androgenic alopecia: a randomized placebo controlled clinical trial

Protocol summary

Study aim

Evaluating the effects of herbal products Henna, Myrtus communis and Mastica on men's androgenic alopecia

Design

A randomized controlled clinical trial with parallel groups, double blinded

Settings and conduct

The research is going to be conducted at the Research and Training Center for Dermatology and Leprosy. Both treatments are the same in appearance and packaging; and can only be differentiated by pharmaceutical codes on the boxes. The patient and the prescriber are not aware of the codes definition.

Participants/Inclusion and exclusion criteria

Inclusion criteria: men aged 18 to 60 years old; type 1 to 3 hair loss according to the Hamilton Hair Loss Criterion that has lasted more than 6 months; participants enrollment approval. Exclusion criteria: having sensitivity to components used in this study; history of G6PD; records of utilizing any topical products to prevent hair loss or stimulate hair growth; 5- α -reductase inhibitors and taking anti-androgenic drugs in the past 2 months; records of systemically given steroids for more than 14 days in the past 2 months; any active diseases in the head including scalp infection in the past 6 months; records of uncontrolled blood pressure or hypotension; any type of cancer or autoimmune diseases and hair transplantation.

Intervention groups

Intervention group: traditional-medical lotion containing Henna leaf, Case leaf, Amla fruit, Mastic, 15 drops, twice a day, for 3 months. control group: 5% of hydro-alcoholic based drug as a placebo; same treatment as intervention group.

Main outcome variables

Number of hair strands; Terminal hairs to Volos; Hairs' diameter; Physician satisfaction with treatment; Patient

satisfaction of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201010048979N1**

Registration date: **2020-11-03, 1399/08/13**

Registration timing: **prospective**

Last update: **2020-11-03, 1399/08/13**

Update count: **0**

Registration date

2020-11-03, 1399/08/13

Registrant information

Name

Marzieh Akhbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

akhbari-m@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-20, 1399/09/30

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of herbal product based on henna (low sonia inermis), Myrtus communis and mastica(pistacia lentiscus) on men's androgenic alopecia: a randomized placebo controlled clinical trial

Public title

Effect of a herbal product on men's androgenic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men aged 18 to 60 years old Type 1 to 3 hair loss according to the Hamilton Hair Loss Criterion that has lasted more than 6 months Patient approval to participate in the study

Exclusion criteria:

Having sensitivity to any of the components use in this study History of G6PD Records of using any typical products to prevent hair loss or stimulate hair growth in the past 2 months Utilizing 5 α reductase inhibitors in the past 2 months Records of taking anti-androgenic drugs in the past 2 months Records of systemically taken steroids for more than 14 days in the past 2 months Any records of uncontrolled blood pressure or hypotension Any active diseases in the head including scalp infection in the past 6 months Records of any types of cancer or autoimmune diseases Any records of hair transplantation

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

The assigning treatments method to patients is randomized and based on randomly permuted blocks with the block size of 6(using the related table to random permutations). The randomized list is provided by a statistical consultant. In this way, the group code of each patient who enters the study (in the order of patient admission) is determined based on a randomized list. These codes, which belong to the two groups of the traditional-medical lotion based on Henna and placebo have been determined by a statistical consultant; and in addition to patients, the researcher will not be informed until the end of the study so that can be conducted as a double blinded study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medication and placebo are identical in terms of appearance a packaging, only differentiated through the proprietary codes set by the pharmacist on the box of medicine. The patient and the prescribing researcher are not aware of the code. The outcomes of the study are prepared by the researcher who is unaware of the grouping and is blind to the groups and type of medications.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Vice-chancellor in research affairs- Tehran University of Medical Sciences

Street address

Sixth Floor, Vice Chancellor for Research and Technology, Ghods Ave., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-04-27, 1399/02/08

Ethics committee reference number

IR.TUMS.VCR.REC.1399.294

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

Androgenic alopecia

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

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

Number of hair strands

Timepoint

Before intervention, 12 weeks after the intervention

Method of measurement

Trichoscan

2

Description

Terminal hair to Volos hair

Timepoint

Before intervention, 12 weeks after the intervention

Method of measurement

Trichoscan

3

Description

Hairs' diameter

Timepoint

Before intervention, 12 weeks after the intervention

Method of measurement

Trichoscan

4

Description

Physician satisfaction with treatment

Timepoint

Before intervention, 6 and 12 weeks after the intervention

Method of measurement

questionnaire

5

Description

Patient satisfaction with treatment

Timepoint

Before intervention, 6 and 12 weeks after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Traditional-medical lotion containing henna leaf, case leaf, amla fruit, mastic, 15 drops, twice a day, for 3 months

Category

Treatment - Drugs

2

Description

Control group: 5% of hydro-alcoholic based drug as a placebo, 15 drops, twice a day, for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Marzieh Akhbari

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Center for Research and Training in Skin Diseases and Leprosy, N.79, Taleghani Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

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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

Tehran 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

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mentalhealth8981@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Marzieh Akhbari

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be a plan to
make this available**Study Protocol**Undecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**Undecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**Undecided - It is not yet known if there will be a plan to
make this available**Analytic Code**Undecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**Undecided - It is not yet known if there will be a plan to
make this available