Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

A camparative study effectiveness topical minoxidil nanosuspention and minoxidil 2% solution in the treatment of alopecia androgenetic

Protocol summary

Study aim
Comparison of the Effect of Minoxidil Nanosulfanation with 2% Minoxidil Solution on the Market for the Treatment of Androgenetic Olopecia

Design
Clinical practice, community-based and pragmatic control group, with parallel, blind, randomized groups

Settings and conduct
This test is done at the Haj Dai Clinic of Kermanshah. At the time of 0, 2, 4, and 6 months, the hair density, hair stroke diameter and overall satisfaction of the patient and blind researcher are measured from the overall growth of the hair.

Participants/Inclusion and exclusion criteria
140 patients with androgenetic alopecia at the age of 18 to 55 years are enrolled in the study. People taking medications such as systemic corticosteroids, anti-androgens, or pregnant and lactating patients are excluded.

Intervention groups
Patients are divided into two groups equally and randomly divided into a group of minoxidil nanoparticles and the other 2% of the 2% solution of minoxidil is available on the market. The two groups receive 2 times daily for 6 months each day from the solution given to them. Is used

Main outcome variables
Hair stalk diameter, hair density, hair growth, headache, erythema, scaling, itching, folliculitis, hirsutism, Hypo-hyperpigmentation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180120038450N1**
Registration date: **2018-07-10, 1397/04/19**
Registration timing: **registered_while_recruiting**
Last update: **2018-07-10, 1397/04/19**
Update count: **0**

Registration date
2018-07-10, 1397/04/19

Registrant information

Name
Shahla Mirzaeei

Name of organization / entity

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Iran (Islamic Republic of)

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+98 83 3824 0526

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-13, 1397/03/23

Expected recruitment end date
2019-06-13, 1398/03/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A camparative study effectiveness topical minoxidil nanosuspention and minoxidil 2% solution in the treatment of alopecia androgenetic

Public title
A camparative study effectiveness topical minoxidil nanosuspention and minoxidil %2 solution in the treatment of alopecia androgenetic

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Signature of written consent for participation in the study 2-Age between 18-55 years 3-The presence of alopecia androgenetic in male or female 4-There is no other disorder that causes hair loss such as telogeny, echolinate or scarring hair (like lichen planus) Class 1-4 in the Fitzpatrick Classification for Skin Type and Grade 3-6 Hair Loss for Men in the Norwood Hamilton Classification and Grade 2-3 Hair Loss for Women in the Ludwing Classification, Non-Use of Finasteride, Anti-Androgenetics, Local Estrogen , Progesterone, tamoxifen, anabolic steroids, potent potent medications for hyperkeratosis, oral glucocorticoid, lithium, phenothiazines within 3 months before the start of the study

Exclusion criteria:

1-Pregnancy 2-lactation 3-Using of anabolic steroids in the last 6month 4-Using of topical minoxidil in the last 6month 5-Using of antiandrogenetic drugs in the last 6 month 6-Using of the drugs who make hyper keratosis as like as systemic corticosteroids in the last 6 month 7-Dont be principled to curative protocol 8-Hair transplantation 9-Collagen vascular disease or HIV 10-Endocrinopathy like PCO, Hypotyroid

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

140 patients are randomly divided into two groups of 70 people

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, the prescribing physician, the data collector, the prospector who is developing, the one who evaluates the outcomes, and who analyzes the data, are unaware of the type of drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Central Office of Kermanshah University of Medical Sciences-Shahid Beheshti Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6714858743

Approval date

2018-06-13, 1397/03/23

Ethics committee reference number

IR.KUMS.REC.1397.138

Health conditions studied

1

Description of health condition studied

alopecia areata

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hair density

Timepoint

0,2,4,6 months

Method of measurement

Phototyrographic method

2

Description

Diagonal hair shaft

Timepoint

0,2,4,6

Method of measurement

Phototyrographic method

3

Description

Patient satisfaction

Timepoint

2,4,6 months

Method of measurement

questionnaire

Secondary outcomes

1

Description
Headache
Timepoint
2,4,6 months
Method of measurement
Ask the patient

2

Description
Erythema - redness-itching
Timepoint
0,2,4,6 month
Method of measurement
Ask the patient

3

Description
Hypopigmentation, hyperpigmentation
Timepoint
0,2,4,6 month
Method of measurement
Evaluate by observation and Ask the patient

Intervention groups

1

Description
Intervention group: Topical minoxidil nanosuspention
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک ویژه پوست حاج دایی
Full name of responsible person
شهلا میرزایی
Street address
pharmacy school, Parastar Bolvar, Daneshga Ave, shirodi bolvar, Kermanshah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Shahla Mirzaeei
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact

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Associate professor

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Person responsible for updating data

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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