

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Efficacy comparison between oral saw palmetto and oral finasteride in treating androgenetic alopecia in male patients

Protocol summary

Summary

Androgenetic alopecia is the most common cause of hair loss and can adversely affect the self-image and self-confidence of the suffering individuals. The relatively few number of approved medications which may not be effective in all subjects or tolerable by all those who take them has resulted seeking for new treatment modalities. Saw palmetto (*Serenoa repens*), a herbal medication primarily used for the treatment of benign prostate hyperplasia (BPH) due to its 5- α -reductase inhibitory effects, is one of the over-the-counter supplements that has been widely used by individuals all around the world to treat hair-loss. This study is a triple-blinded RCT aimed at determining the true effectiveness and potential side-effects of this herbal medicine by its comparison with its synthetic counterpart finasteride. 40 male subjects with androgenetic alopecia, between 18-41 years of age and with no history of internal diseases or consumption of medications effective on scalp hair growth for 1 year enter the study. Subjects are then randomly allocated to either the oral saw palmetto 320 mg/d or the oral finasteride 1 mg/d group. Treatment is continued for 6 months. Before and after the treatment the number of hair follicle units are counted in a photograph of 1 cm² area of the sagittal scalp. The participants, the physician who prescribes the medications and the physician who counts the hair follicles and grades the degree of alopecia, are all blinded to the subject's medication. The scoring physician is also blinded to the stage of therapy (i.e. before or after). Occurrence of side-effects that are life threatening or intolerable by the subjects, as well as self-willed discontinuation of the medications or concurrent use of other treatments which can potentially affect hair growth are considered as major exclusion criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102011170N1**

Registration date: **2013-06-12, 1392/03/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Pardis Hejazi

Name of organization / entity

Tehran University of Medical Sciences, Razi
Dermatology Hospital

Country

Iran (Islamic Republic of)

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+98 21 5563 0669

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p-hejazi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of
Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy comparison between oral saw palmetto and oral finasteride in treating androgenetic alopecia in male patients

Public title

Comparison of the effectiveness of oral herbal supplement saw palmetto with finasteride in treatment of male pattern hair-loss

Purpose

Treatment

Inclusion/Exclusion criteria

Healthy male subjects between 18 to 41 years old with grade 1 or higher androgenetic alopecia (according to Hamilton-Norwood criteria) without any systemic diseases or organ dysfunction who seek for treatment of their balding scalp that have no history of taking medications effective on hair-growth or hair-loss during the past year and who consent to be included in the trial. Exclusion criteria include: occurrence of potentially life-threatening side-effects or any adverse effect that is not tolerable by the patient, discontinuation of the medication or intentional use of other medications concurrently which are effective on hair growth.

Age

From **18 years** old to **41 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in research committee of Tehran University of Medical Sciences

Street address

Room 105, 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Postal code

Approval date

2012-08-14, 1391/05/24

Ethics committee reference number

130/1049/91/5

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64

ICD-10 code description

Male-pattern baldness

Primary outcomes

1

Description

Number of hair follicles in one centimeter square of the sagittal scalp

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Cutting the hair in one centimeter area of a specified area of the scalp and photography from this region for counting the hair follicles

Secondary outcomes

1

Description

Aspartate transaminase

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

2

Description

Alanine transaminase

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

3

Description

Alkaline phosphatase

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

4

Description

Bilirubin (total)

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

5

Description

Bilirubin (direct)

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

6

Description

Amylase

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

7

Description

Lipase

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

8

Description

Triglyceride

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

9

Description

total cholesterol

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

10

Description

Low density lipoprotein

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

11

Description

High density lipoprotein

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

12

Description

Partial thromboplastine time

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

13

Description

International normalized ratio

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

14

Description

bleeding time

Timepoint

before and 6 month after the intervention

Method of measurement

by coagulation technologist

15

Description

total testosterone

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

16

Description

free testosterone

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

17

Description

Dihydrotestosterone

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

18

Description

Prostate specific antigen

Timepoint

before and 6 month after the intervention

Method of measurement

measurement in serum

19

Description

Gastrointestinal symptoms

Timepoint

before and 6 month after the intervention

Method of measurement

interview with the patient

20

Description

sexual function

Timepoint

before and 6 month after the intervention

Method of measurement

interview with the patient

Intervention groups

1

Description

Intervention group: Oral consumption of saw palmetto extract 320 mg daily for 6 months

Category

Treatment - Drugs

2

Description

Control group: Consumption of oral finasteride 1 mg daily for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Dermatology Hospital

Full name of responsible person

Dr. Pardis Hejazi, resident of dermatology

Street address

Razi Dermatology Hospital, Vahdat Eslami sq. ,
Vahdat Eslami ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reasearch of Tehran University of
Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central Construction of Tehran University of Medical
Sciences, Ghods intersection, Keshavarz blvd. Vice
chancellor for reasearch of Tehran University of
Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for reasearch of Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Razi Dermatology Hospital

Full name of responsible person

Dr. Pardis Hejazi

Position

MD, resident of dermatology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Razi Dermatology Hospital

Full name of responsible person

Dr. Hossein Mortazavi

Position

Associate Professor

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty