Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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 it's 5-a-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 it's comparison with it's 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 sagital 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 potantially 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 Siences, Razi Dermatology Hospital
Country
Iran (Islamic Republic of)
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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: occurence of potentially life-threatening side-effects or any adverse effect that is not tolerable by the patient, discontinuation of the edication 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/د

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 squar of the sagital scalp
Timepoint
Before the intervention and 6 months after the intervention
Method of measurement
Cutting the hair in one centimeter area of an 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
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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Associate Professor

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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