Protocol summary

Study aim
The effect of Biotin and Dexpanthenol on hair loss in patients with androgenetic alopecia

Design
Clinical trials with control group, with parallel groups, not blind

Settings and conduct
Patients with types 1 to 4 of androgenetic hair loss referring to the dermatology department of Tabriz Sina Hospital were divided into 2 intervention and a control groups. The control group received Minoxidil 5% solution and Finasteride 1mg tablets. In the first intervention group, in addition to the above drugs, the injectable Biotin was used and in the second group, in addition to the base treatment, Biotin and Dexpanthenol Was prescribed. All three groups will be checked monthly in terms of reducing hair loss and increasing the number and thickness of hair within 3 months.

Participants/inclusion and exclusion criteria
Inclusion criteria: male; age 18-50; androgenetic alopecia type 1-4. Non-inclusion criteria: Having varicocele; Willing to get pregnant.

Intervention groups
Patients with androgenic alopecia type 1 to 4 will be divided into a control group and two intervention groups. Control group: Minoxidil 5% solution and Finasteride 1mg tablets were prescribed. Intervention group 1: Minoxidil 5% solution and Finasteride 1mg tablets and Biotin ampoules were prescribed. Intervention group 2: Minoxidil 5% solution and Finasteride 1mg tablets and Biotin and Dexpanthenol ampoules were prescribed.

Main outcome variables
Hair loss; the number and thickness of hair

General information
Reason for update
Acronym
IRCT registration information
alopecia

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Men with androgenetic hair loss type 1 to 4

**Exclusion criteria:**
Having varicocele Willing to get pregnant

**Age**
From 18 years old to 50 years old

**Gender**
Male

**Phase**
2-3

**Groups that have been masked**
No information

**Sample size**
Target sample size: 90
Actual sample size reached: 84

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2018-09-04, 1397/06/13

Ethics committee reference number
IR.TBZMED.REC.1397.466

**Health conditions studied**

1

**Description of health condition studied**
Androgenic alopecia

**ICD-10 code**
L64.8

**ICD-10 code description**
Other androgenic alopecia

**Primary outcomes**

1

**Description**
Score of hair loss

**Timepoint**
Measuring hair loss at the beginning of the study (before the intervention) and 30, 60 and 90 days after the start of the medication

**Method of measurement**
Monthly scoring for hair loss of 10 based on patient’s claim

2

**Description**
The hair thickness

**Timepoint**
Measuring the thickness of the hair at the beginning of the study (before the intervention) and 30, 60 and 90 days after the start of the medication

**Method of measurement**
Trichoscope

3

**Description**
The number of hair in a circle 2.54 cm in diameter

**Timepoint**
Counting the number of hair at the beginning of the study (before the intervention) and 30, 60 and 90 days after starting the medication

**Method of measurement**
Macrophotography technique

**Secondary outcomes**
empty

**Intervention groups**

1

**Description**
Control group: Minoxidil solution 5%, produced by Pak darou inc, 20 drops, twice a day, for 3 months and finasteride 1 mg tablet, produced by Shafa inc, 1 tablet daily for 3 months

**Category**
Treatment - Drugs
2

Description
Intervention group 1: Minoxidil solution 5%, produced by Pak darou inc, 20 drops twice a day for 3 months and Finasteride tablet 1 mg, produced by Shafa inc, 1 tablet daily for 3 months and Biotin IM injections 5 mg / ml, produced by Oxin darou vesht, every 5 days for 3 months.

Category
Treatment - Drugs

3

Description
Intervention group 2: Minoxidil solution 5% of the Pak darou inc, twice daily 20 drops for 3 months and Finasteride tablet 1 mg of Shafa inc, 1 tablet daily for 3 months and biotin ampoule 5 mg / ml Oxin darou vesht every 5 days for 3 months (IM) And dexpantol ampoule 500 mg / 2 ml each. Oxin darou vesht every 5 days for 3 month (IM)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital affiliated to Tabriz University of Medical Sciences

Full name of responsible person
Sanaz Ghasempour

Street address
Sina hospital, Azadi street, Tabriz

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Tabriz

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East Azarbaijan

Postal code
5163639888

Phone
+98 41 3541 2101

Email
research-vice@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

Street address
Tabriz University of Medical Sciences, Daneshgah street, Tabriz

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5166614766

Phone
+98 41 3337 2250

Email
ajouyban@hotmail.com

Web page address
https://pharmfac-en.tbzmed.ac.ir/teacher/Abolghasem%20Jouyban

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
50

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

2

Sponsor
Name of organization / entity
Oxin darou Vesht

Full name of responsible person
Mohammadreza Bahiraei

Street address
No. 85, Saman Ave, South Shiraz street, Vanak square, Tehran

City
Tehran

Province
Tehran

Postal code
1435853385

Phone
+98 21 8862 2899

Email
info@oxindarouvesht.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oxin darou Vesht

Proportion provided by this source
50

Public or private sector
Private

Domestic or foreign origin
Domestic
**Person responsible for general inquiries**

Contact

Name of organization / entity  
Tabriz University of Medical Sciences

Full name of responsible person  
Sanaz Ghasempour

Position  
pharmacy student

Latest degree  
A Level or less

Other areas of specialty/work  
Medical Pharmacy

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**Person responsible for updating data**

Contact

Name of organization / entity  
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Full name of responsible person  
Sanaz Ghasempour

Position  
pharmacy student

Latest degree  
A Level or less

Other areas of specialty/work  
Medical Pharmacy

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Email  
ghasempour_sanaz@yahoo.com

**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