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

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

IRCT registration number: IRCT20190430043438N1
Registration date: 2019-06-17, 1398/03/27
Registration timing: retrospective

Last update: 2019-06-17, 1398/03/27
Update count: 0

Registration date
2019-06-17, 1398/03/27

Registrant information
Name
Sanaz Ghasempour

Name of organization / entity
Country
Iran (Islamic Republic of)

Phone
+98 41 3327 4650

Email address
ghasempour_sanaz@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-06, 1397/09/15

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
2018-12-16, 1397/09/25

Actual recruitment end date
2019-03-16, 1397/12/25

Trial completion date
2019-05-18, 1398/02/28

Scientific title
The effect of Biotin and Dexpanthenol on hair loss in patients with androgenetic alopecia

Public title
The effect of Biotin and Dexpanthenol on androgenetic
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
City
Tabriz
Province
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
City
Tabriz
Province
East Azarbaijan
Postal code
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

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

City
- Tabriz

Province
- East Azarbaijan

Postal code
- 5166614766

Phone
- +98 41 3335 5921

Email
- ghasempour_sanaz@yahoo.com

Person responsible for updating data

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
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Province
- East Azarbaijan

Postal code
- 5166614766

Phone
- +98 41 3335 5921

Email
- info@pharmfac.tbzmmed.ac.ir

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