

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Oct 2021

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 androgenic 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 dexantol 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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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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<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

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Tehran

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1435853385

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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

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Yadollah Azarmi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

A Level or less

Other areas of specialty/work

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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