

# 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, 1tablet 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

##### 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

**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

**Street address**

Tabriz University of Medical Sciences, Daneshgah street, Tabriz

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**Phone**

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**Email**

ghasempour\_sanaz@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Yadollah Azarmi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Email**

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**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

**Other areas of specialty/work**

Medical Pharmacy

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**City**

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**Postal code**

5166614766

**Phone**

+98 41 3335 5921

**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