

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Gel Formulation of Trigonella foenum-graceum Seed on prevention of trichoptilosis in randomized placebo controlled Clinical Trial

Protocol summary

Study aim

Evaluation of Gel Formulation of Trigonella foenum-graceum Seeds on prevention of trichoptilosis in randomized placebo controlled Clinical Trial

Design

The total volume of the sample is 60 persons, which half of them is in the control and half of them is in the drug recipient group. The selection of the patients associated with the study will do by a dermatologist . The study is done in two- blind . People should not have any hair-related illnesses, including metabolic diseases, etc. Use of any hair products during treatment Should be under the supervision a dermatologist.

Settings and conduct

The study does under the supervision of a dermatologist at touba medical center . The randomized coded products are given to patients.

Participants/Inclusion and exclusion criteria

Patients by the age ranging 20 and 50 years should not have any hair-related illnesses including metabolic diseases, etc.

Intervention groups

The study consists of two groups of placebo and drug recipients .The intervention group received a medicinal gel containing the extract and the placebo or control group received an extract-free gel. The gels were rubbed daily by the individual to the entire hair and not allowed to be showered for 12 hours.

Main outcome variables

Checking of Improvement in Patients with trichoptilosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130911014630N4**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **retrospective**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

Registrant information

Name

Mohammad Azadbakht

Name of organization / entity

Mazandaran University of Medical Scinecee

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3728

Email address

mazadbakht@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

governmental

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Gel Formulation of Trigonella foenum-graceum Seed on prevention of trichoptilosis in randomized placebo controlled Clinical Trial

Public title

Evaluation of Gel Formulation of Trigonella foenum-graceum Seed on prevention of trichoptilosis in randomized placebo controlled Clinical Trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Age 20-50 Man or woman Selection of patients without prior knowledge and based on their referral to a specialist physician The patient has an impairment trichoptilosis The patient has a disorder of personal satisfaction with the use of the product

Exclusion criteria:**Age**

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, individual, using random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, dermatologist, and dermatologist, as well as the placebo or drug product, have no information about the product and the products have been pre-determined and randomly assigned to the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University Of Medical Sciences

Street address

Mazandaran University of Medical Sciences - Sari

City

Sari

Province

Mazandaran

Postal code

-

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.MAZUMS.REC.1396.2909

Health conditions studied**1****Description of health condition studied**

Trichoptilosis

ICD-10 code

L67.8

ICD-10 code description

Other hair colour and Hair shaft abnormalities

Primary outcomes**1****Description**

Trichoptilosis

Timepoint

At least 2 times in week along 2 month

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

calvities

Timepoint

At least 2 times in week along 2 month

Method of measurement

Questinnnaire

Intervention groups**1****Description**

Intervention group: The gel contains 5 grams extract of seeds of fenugreek used Twice daily , so that the whole hair should be covered . Do not shave 12 hours after use .To this end, 30 patients are selected according to the conditions of entry.They are given the drug gel formulation containing fenugreek seed extract for two months under the supervision of a dermatologist and in collaboration with the presenter.Herbal gel contains 5% fenugreek seed extract.To prepare 100 cc of gel, 0.02 grams of propyl paraben, 0.18 grams of methyl paraben, 1 gram of carbapl 980, 5 milliliters of glycerin, Small amount of 1% NaOH solutionn and up to 100 cc of distilled water, UP is used. It is expected that the extract of Fenugreek seed with its effect on the cuticle structure of the hair will increase its strength and reduce the bulging of the ends of hair shafts. This gel was made in the lab of the Mazandaran -Sari Pharmaceutical Faculty.

Category

Prevention

2

Description

Control group: The placebo gel contains all the ingredients of the drug gel except for the fenugreek seed extract. The method of use is the same as druged gel. It is used twice daily and Do not shave 12 hours after use. To this end, 30 patients are selected according to the conditions of entry. They are given the placebo gel formulation for two months under the supervision of a dermatologist and in collaboration with the presenter. It is expected that this gel does not have a significant effect, unlike the druged gel. This gel was made at the laboratory of the Mazandaran -Sari Pharmaceutical Faculty.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba Medical Center - Mazandaran University of Medical Science

Full name of responsible person

Dr. Mohammad Azadbakht - Dr. Ghasem Rahmatpour Rokni

Street address

Tuba Medical Center, Farah Abad Square, Khazar Boulevard, Sari, Mazandaran, Iran

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Email

Azadbakhtm@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Science- Sari - Mazandaran - Iran

Full name of responsible person

Dr. Mohammad Azadbakht

Street address

Pharmacy College - Payambar Azam Medicinal Complex - Sari - Mazandaran - Iran

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Mazandaran

Postal code

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Email

Azadbakhtm@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Science- Sari - Mazandaran - Iran

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medicinal Science- Sari- Iran

Full name of responsible person

Majid Hajizadeh

Position

Pharmacy Student of Pharmacy College

Latest degree

A Level or less

Other areas of specialty/work

Street address

Pharmacy College - Payambar Azam Medicinal Complex - Sari - Mazandaran - Iran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Science- Sari

Full name of responsible person

Dr. Mohammad Azadbakht

Position

Pharmacognosy Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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+98 935 183 2770

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Majidhajizadeh_72@Yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Results from clinical trials

When the data will become available and for how long

Start access after printing the article

To whom data/document is available

Access for scholars working in academic institutions

Under which criteria data/document could be used

Use of results is allowed only by mentioning its source

From where data/document is obtainable

azadbakhtm@hotmail.com

What processes are involved for a request to access data/document

Request from the researcher

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

Mazandaran University of Medicinal Science-Sari

Full name of responsible person

Majid Hajizadeh

Position

Pharmacy Student Of Pharmacy College -Sari

Latest degree

A Level or less

Other areas of specialty/work**Street address**

Payambar Azam Medicinal Complex-Pharmacy
College - Sari

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Province

Mazandaran

Postal code

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