Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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 Commitee 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
Questinnaire

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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Sari

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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 Azadbkht

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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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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Person responsible for updating data

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Full name of responsible person
Majid Hajizadeh
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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