Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of the slow release fenugreek (Trigonella foenum-graecum) seed formulation on pain relief in patients with temporomandibular disorder

Protocol summary

Study aim
1.Determine the mean pain in standard group for 14 days 2.Determine the mean pain in fenugreek group for 14 day 3.Comparison of pain score in both groups 4.Comparison of pain relief in both groups 5.Comparison of drug side effects between the two groups on the 28th day

Design
Two arm parallel group, randomized trial and blinded outcome assessment

Settings and conduct
This study will be performed in Oral and Dental department of Kerman University of Medical Sciences. only researchers are not blinded in this study.

Participants/Inclusion and exclusion criteria
inclusion criteria: 1.Men and women over than 14 year old 2.Patients who are able to answer Questionnaire forms 3.Patients who want to enter the study exclusion criteria: 1.Pregnancy and Lactation in women 2.diabetic patients 3.Digestive disorders 4.Patient who takes statin 5.The patients who have allergic reaction to fenugreek 6.Patients with history of coagulation disorders

Intervention groups
Capsules containing fenugreek seed extract tablets are given as two 600 mg capsules daily and positive control group will be received capsule containing 500 mg naperoxen twice a day because of long duration of an action and low risk of cardiovascular disease

Main outcome variables
Evaluation of chronic pain relief in patients for 14 days by using VAS questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181218042039N1**
Registration date: **2019-04-27, 1398/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**
Update count: **0**

Registration date
2019-04-27, 1398/02/07

Registrant information

Name
Sara Hashemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3211 1249

Email address
sara96hashemi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-01, 1397/12/10

Expected recruitment end date
2019-07-01, 1398/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the slow release fenugreek (Trigonella foenum-graecum) seed formulation on pain relief in patients with temporomandibular disorder

Public title
fenugreek extract effect on pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women over 14 years of age Patients who be able to respond to the mentioned forms Patients wishing to enter the study

Exclusion criteria:

Pregnancy and lactation in women Patients with Diabetes Mellitus patients who take statin drugs Sensitivity to Fenugreek or other herbs Patients with history of coagulation disorders Patients undergoing orthodontic or orthopedic procedures Patients treated with anti psychotropic, anti-inflammatory and analgesic drugs and splint therapy Patients with dental caries that imitate pain in the head and face Patients with periodontal problems Patients with pathologic problems in the head and face

Age

From **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the studied and the standard drug in dosage form and packaging are quite similar. Each label has A or B letter that is known by investigator which letter belong to the studied or standard drug.Each patient receives only one arbitration package. After explaining the study process, the patients will be told that the chance of being in each group will be one second and after signing the consent form, with full knowledge of the research process, they will be included in the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Deputy of research and technology, Student research committee, Tahmasebad acrossroads, beginning at Ibn Sina street

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.KMU.REC.1397.355

Health conditions studied

1

Description of health condition studied

Temporomandibular disorders

ICD-10 code

M26.60

ICD-10 code description

Temporomandibular joint disorder, unspecified

Primary outcomes

1

Description

reduce pain in Visual Analogue Scale and Brief Pain Inventory questionnaire

Timepoint

at beginning of the study and after 14th , 28th days of the beginning of the study

Method of measurement

Visual Analogue Scale and Brief Pain Inventory of pain questionnaire

Secondary outcomes

1

Description

GI upset

Timepoint

Two and four weeks after drug administration

Method of measurement

Patient claim and Questionnaire fullfilment

Intervention groups

1

Description

Intervention group: Fenugreek seed extract, with amount

of 600 mg in each capsule, twice a day, in two weeks, once every 12 hours, after meal

Category

Treatment - Drugs

2

Description

Control group: naproxen capsules, with amount of 500 mg in each same capsules, twice a day, in two weeks, once every 12 hours, after meal, Pars darou company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry

Full name of responsible person

Goli Ghamani and Reza Zarei

Street address

Faculty of Dentistry, end of Shafa Boulevard, Kerman, Kerman Province

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3211 9021

Fax

+98 34 3211 8073

Email

dentistryschool@kmu.ac.ir

Web page address

http://kmu.ac.ir/fa/sd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Kerman University of Medical Sciences, Deputy of research and technology, Student research committee, Tahmasebi acrossroads, beginning at Ibn Sina street

City

Kerman

Province

Kerman

Postal code

761981555

Phone

+98 34 3226 3855

Fax

+98 34 3226 3855

Email

research@kmu.ac.ir

Web page address

http://kmu.ac.ir/fa/vcrt

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

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

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ansari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

761913555

Phone

+98 34 3132 5022

Fax

+98 34 3132 5003

Email

mansari@kmu.ac.ir

Person responsible for scientific inquiries

Contact

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Kerman University of Medical Sciences

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Person responsible for updating data

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Fax
+98 34 3132 5003

Email
mansari@kmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The results may show effectiveness of the drug, therefor we want to make patent.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available