

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Pregabalin for the treatment of subacute and chronic refractory cough

Protocol summary

Study aim

To study the effect of Pregabalin for the treatment of subacute and chronic refractory cough

Design

Randomized controlled trial, with two arm parallel group of 30 patients, will be enrolled between May 2019 and December 2019, and will follow for 2 weeks.

Settings and conduct

In this research, 30 eligible patients with subacute or chronic refractory cough referring to Shahid Beheshti Hospital of Qom were chosen. Then, patients by block randomization were randomly divided into two control and intervention groups. The intervention group will receive pregabalin capsule and control group will receive placebo capsule. Participants and outcome assessor does not know the intervention type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: subacute cough (between 3 and 8 weeks) or chronic cough. Exclusion criteria: history of asthma, history of chronic bronchitis pneumonia, pulmonary abscess or pulmonary tuberculosis, smokers

Intervention groups

Intervention group: pregabalin capsule, oral, 150 mg, every 12 hours for two weeks. Control group: placebo capsule, oral, every 12 hours for two weeks

Main outcome variables

Number of cough attacks per day and number of coughs per attack

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170215032587N5**

Registration date: **2019-03-12, 1397/12/21**

Registration timing: **prospective**

Last update: **2019-03-12, 1397/12/21**

Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

Mohammad Aghaali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 751 5639

Email address

maghaali@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pregabalin for the treatment of subacute and chronic refractory cough

Public title

Pregabalin for the treatment of cough

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subacute cough (between 3 and 8 weeks) or chronic cough

Exclusion criteria:

History of asthma History of chronic bronchitis

Pneumonia, pulmonary abscess or pulmonary tuberculosis Smokers

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be assigned to two groups of intervention and control by block randomization. For this purpose blocks of size 4 will be used. Six blocks will include BAAB, ABBA, BABA, BBAA, ABAB, AABB. To hide the random allocation, the numbered dark envelopes will be used, in which the group name is specified in the random sequence generated. Then, according to the order of entering samples, for the first patient the envelope number one is opened and the group will be identified until the end.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and outcome assessor does not know the allocation

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom

City

Qom

Province

Ghoum

Postal code

3716987366

Approval date

2019-01-29, 1397/11/09

Ethics committee reference number

IR.MUQ.REC.1397.168

Health conditions studied

1

Description of health condition studied

Cough

ICD-10 code

R05

ICD-10 code description

Cough

Primary outcomes

1

Description

Number of cough attacks per day

Timepoint

7 and 14 days after intervention

Method of measurement

Patient statement

2

Description

Number of coughs per attack

Timepoint

7 and 14 days after intervention

Method of measurement

Patient statement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pregabalin capsule, oral, 150 mg, every 12 hours for two weeks

Category

Treatment - Drugs

2

Description

Control group: placebo capsule, oral, every 12 hours for two weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Seyed Hasan Adeli

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd, Qom

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2053

Email

adeli@muq.ac.ir

Full name of responsible person

Seyed Hasan Adeli

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street addressQom University of Medical Science, Saheli Street,
Qom**City**

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3285 2720

Email

Adeli@muq.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom

City

Qom

Province

Ghous

Postal code

3716987366

Phone

+98 25 3285 2720

Email

hsaghafi@muq.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ghous 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**

Ghous University of Medical Sciences

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

Ghous University of Medical Sciences

Full name of responsible person

Seyed Hasan Adeli

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street addressQom University of Medical Science, Saheli street,
Qom**City**

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3285 2720

Fax**Email**

Adeli@muq.ac.ir

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

Ghous University of Medical Sciences

Full name of responsible person

Seyed Hasan Adeli

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Qom University of Medical Science, Saheli Street,
Qom

City

Qom

Province

Ghoum

Postal code

3713649373

Phone

+98 25 3285 2720

Email

Adeli@muq.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 data are specific to this study

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