Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 whit 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
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Mohammad Aghaali
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
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Seyed Hasan Adeli
Position
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Latest degree
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Person responsible for updating data

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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