Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Effects of Anti-reflux Therapy with Omeprazole on Gastrointestinal and Respiratory Symptoms in Victims of Mustard Gas Exposure with Chronic Cough

Protocol summary

Summary

We aimed to evaluate the effects of anti-reflux therapy with omeprazole on gastrointestinal and respiratory symptoms in warfare victims of exposure to mustard gas with chronic cough. Study was conducted on 60 Iranian chemical warfare victims with a history of exposure to mustard gas and symptoms of chronic cough (more than 3 weeks) and GERD between 2008 and 2011. Current smokers and those with previous history of smoking and also those under recent anti-reflux therapy were not included. Patients were randomized to receive omeprazole (20 mg twice daily) for four months followed by one month washout and four months of placebo (OP), or the reverse treatment (PO). Assessments included GERD and cough symptoms as primary outcomes, and quality of life, and pulmonary function using spirometry as secondary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072510398N1**
Registration date: **2012-08-17, 1391/05/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-17, 1391/05/27

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences, Chemical Injuries Research Cennter

Expected recruitment start date

2008-01-01, 1386/10/11

Expected recruitment end date

2011-01-01, 1389/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Anti-reflux Therapy with Omeprazole on Gastrointestinal and Respiratory Symptoms in Victims of Mustard Gas Exposure with Chronic Cough

Public title

Treatment of Gastro-esophageal Reflux Disease in Victims of Mustard Gas Exposure with Chronic Cough

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male; Chemical warfare victim; Having a history of exposure to mustard gas; Having symptoms of chronic cough (more than 3 weeks); Having symptoms of GERD; Willing to participate Exclusion criteria: Current smokers; Having previous history of smoking; Being under recent anti-reflux therapy; Contraindication for

using omeprazole

Age
From **18 years** old to **65 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences

Street address
Molla Sadra Ave., Baqiyatallah University of Medical Sciences

City
Tehran

Postal code

Approval date
2010-08-01, 1389/05/10

Ethics committee reference number
86414

Health conditions studied

1

Description of health condition studied
Gastro-oesophageal reflux disease

ICD-10 code
K21

ICD-10 code description
Gastro-oesophageal reflux disease

Primary outcomes

1

Description
GERD Symptoms

Timepoint
Before and After the Trial

Method of measurement
Questionnaire

2

Description
Cough Symptoms

Timepoint
Every one month

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Quality of Life

Timepoint
Before and After the Trial

Method of measurement
Questionnaire

2

Description
Pulmonary Function

Timepoint
Before and After the Trial

Method of measurement
Spirometry

Intervention groups

1

Description
Omeprazole (20 mg twice daily) for four months followed by one month washout and four months of placebo

Category
Treatment - Drugs

2

Description
Reverse treatment: Placebo twice daily for four months, then one month washout period, then omeprazole 20 mg twice daily for four months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir-Almomenin Hospital
Full name of responsible person
Dr. Mohammad Talaei
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr Mostafa Ghanei
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Molla Sadra Ave., Baqiyatallah University of Medical Sciences
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty