

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Name

Mohammad Hassan Emami

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66801680098311

Email address

mh_emami@med.mui.ac.ir

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

Email
mtalaei@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences, and Poursina
Hakim Research Institute
Full name of responsible person
Dr. Mohammad Hassan Emami
Position
MD, Associate Prof. of Gastroenterology
Other areas of specialty/work
Street address
#23, Fribourg Crossroads, Azadi Ave.
City
Isfahan
Postal code
Phone
+98 31 1668 0168
Fax
Email
mh_emami@med.mui.ac.ir
Web page address

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

Contact

Name of organization / entity
Isfahan University of Medical Sciences and Poursina
Hakim Research Institute
Full name of responsible person
Dr Mohammad Talaei
Position
MD, MPH, Research Assistant
Other areas of specialty/work
Street address
#23, Fribourg Crossroads, Azadi Ave.
City
Isfahan
Postal code
Phone
+98 31 1668 0168
Fax

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences, and Poursina
Hakim Research Institute
Full name of responsible person
Dr. Mohammad Talaei
Position
MD, MPH, Research Assistant
Other areas of specialty/work
Street address
#23, Fribourg Crossroads, Azadi Ave.
City
Isfahan
Postal code
Post Box: 81465-1798
Phone
+98 31 1668 0168
Fax
+98 31 1668 0168
Email
mtalaei@gmail.com
Web page address

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