Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Investigation of the effects of oral curcumin on pulmonary complications due to sulfur mustard exposure

Protocol summary

Summary
The aim of this study is to investigate the efficacy of curcumin on the clinical symptoms and quality of life of patients with chronic respiratory complications due to sulfur mustard exposure. The study population consists of patients with documented pulmonary complications due to sulfur mustard. Patients with respiratory problems due to other factors would be excluded from the study. Patienst (two groups of 40 subjects each) would be treated with a combimation of curcumin (150 mg/day) and piperine (15 mg/day), or placebo. Primary efficacy measures at baseline and at the end of study would be the spirometric parameters and quality of life based on the St. George questionnaire.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2013091114521N2**
Registration date: **2013-12-10, 1392/09/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2013-12-10, 1392/09/19

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

Expected recruitment start date
2012-10-22, 1391/08/01
Expected recruitment end date
2013-10-23, 1392/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the effects of oral curcumin on pulmonary complications due to sulfur mustard exposure

Public title
The effects of curcumin on respiratory problems due to mustard gas
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Documented sulfur mustard exposure and documented respiratory damage due to mustard intoxication. Exclusion: Participation in a concomitant trial; presence of life-threatening disorders; smoking and addiction; cardiovascular disease; lung cancer; pneumonia; acute bronchitis; development of severe drug-related adverse events; use of antioxidant supplements/drugs in the preceding three months; lungectomy and aggravation of symptoms during the course of study.
Age
From **18 years** old to **70 years** old
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Baqiyatallah University of Medicla Sciences Ethics Committee
Street address
Molla-Sadra st, Vanaq sq, Baqiyatallah University of Medical Sciences
City
Tehran
Postal code
91775-1365
Approval date
2012-10-22, 1391/08/01
Ethics committee reference number
8080

2

Ethics committee
Name of ethics committee
Baqiyatallah University of Medicla Sciences Ethics Committee
Street address
Molla-Sadra st, Vanaq sq, Baqiyatallah University of Medical Sciences
City
Tehran
Postal code
Approval date
2012-07-25, 1391/05/04
Ethics committee reference number
340/3/5885

Health conditions studied

1

Description of health condition studied
Chronic respiratory problems due to mustard gas intoxication
ICD-10 code
J68.4
ICD-10 code description
Chronic respiratory conditions due to chemicals, gases, fumes and vapours

Primary outcomes

1

Description
Improvement of patients' quality of life
Timepoint
After four weeks of treatment
Method of measurement
Based on the st. George questionnaire

2

Description
Improvement of respiratory symptoms
Timepoint
After four weeks of treatment
Method of measurement
Based on the CAT questionnaire

Secondary outcomes

1

Description
Changes in serum levels of tumor necrosis factor-alpha
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

2

Description
Changes in serum levels of transforming growth factor-beta
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

3

Description
Changes in serum levels interleukin 6
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

4

Description
Changes in serum levels interleukin 8
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

5

Description
Changes in serum levels of macrophage chemotactic protein-1
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

6

Description
Changes in serum levels of substance P
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

7

Description
Changes in serum levels of C-reactive protein
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

8

Description
Changes in serum levels of calcitonin gene-related peptide
Timepoint
After four weeks of treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

Intervention groups

1

Description
Intervention group: curcumin (1500 mg/day)
Category
Treatment - Drugs

2

Description
Control group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Yunes Panahi
Street address
Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr. Alireza Saadat
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Molla-Sadra st., Vanaq sq., Deputy of Research, 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
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
Chemical Injuries Research Center, Baqiyatallah university of Medical Sciences
Full name of responsible person
Yunes Panahi
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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