

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of low-dose oral Theophylline on serum HS-CRP in patients with stable COPD

Protocol summary

Summary

This study was conducted to determine the effect of oral low dose Theophylline on serum CRP in patients with stable COPD referred to specialized Tohid Hospital clinics and private clinic in Sanandaj 1387. This is a double blind randomized clinical trial study. Fifty patients (25 in experimental group and 25 in placebo group) were enrolled into the study on the basis of block randomization method. Inclusion criteria include stable COPD (no exacerbation in the past two months), FEV1/FVC ratio less than 70%. Serum CRP levels were evaluated by ELISA sensitive HS-CRP method, and then slowly release Theophylline tablets with dose of 200 mg every 12 hours in the intervention group and the placebo in the control group was administered for one month and again at the end of the study HS-CRP was measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808182685N1**

Registration date: **2009-12-05, 1388/09/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-12-05, 1388/09/14

Registrant information

Name

Naseh Sigari

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

naseh46@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Kurdistan University of Medical Sciences

Expected recruitment start date

2008-12-05, 1387/09/15

Expected recruitment end date

2009-03-05, 1387/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low-dose oral Theophylline on serum HS-CRP in patients with stable COPD

Public title

The effect of low-dose oral Theophylline drug on active c serum protein level in patients with stable chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: stable COPD (no exacerbation in the past two months), FEV1/FVC ratio less than 70%.

Exclusion criteria: no smoking history, FEV1 increased more than 200 cc or 12% after administration of 400 micrograms spray Salbutamol in spirometry, clinical or radiographic evidence of pneumonia, history of infectious disease such as tuberculosis, recent respiratory tract infections, bronchiectasis, acute or chronic diarrhea, rheumatoid arthritis, degenerative disease of large joint, vasculitis, and the possibility of malignancy based on

history and examination and Theophylline use during a month prior to the enrollment

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

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

Ethics committee of Kurdistan University of Medical Sciences

Street address

Vice-chancellor for Research, Kurdistan University of Medical Sciences, Pasdaran Street,

City

Sanandaj

Postal code

13446-66177

Approval date

2008-12-22, 1387/10/02

Ethics committee reference number

9045 پ/14/پ

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J40, J43

ICD-10 code description

chronic Bronchitis, Emphysema with FEV1<70

Primary outcomes

1

Description

HS-CRP serum levels

Timepoint

Before and after intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Placebo with dose of 200 mg every 12 hours for one month

Category

Placebo

2

Description

Theophylline tablets, 200 mg every 12 hours for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Dr. Naseh Sigari

Street address

Abidar Street

City

Sanandaj

2

Recruitment center

Name of recruitment center

Pulmonary subspecialty ward, Tohid Hospital

Full name of responsible person

Dr. Naseh Sigari

Street address

Gheryashan Street, Pulmonary subspecialty ward , Tohid Hospital

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Ataollah Haydari

Street address

Vice-chancellor for Research, Kurdistan University of Medical Sciences, Pasdaran Street,

City

Sanandaj

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

Yes

Title of funding source

Vice-chancellor for Research, Kurdistan 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**

Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Naseh Sigari

Position

subspecialist in pulmonary and critical care medicine
/ Assistant Professor of Internal medicine Dep

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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