

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

High dose Rosuvastatin as an adjunctive treatment in acute exacerbation of chronic obstructive pulmonary disease, a randomized double blind clinical trial.

Protocol summary

Summary

Summary: 1. Objective: based on retrospective evidence, Statin therapy in chronic obstructive pulmonary disease (COPD) may have some advantages regarding the outcomes in this disease. 2. Design: the patients presented to emergency department with acute exacerbation of COPD (AECOPD) by random number table will be randomly assigned to receive either high dose Rosuvastatin (40 mg) or placebo for 14 days, . Both groups will receive classic treatment of AECOPD. The patients, physicians (who treat patients based on current guidelines recommendation) and researcher (who gathers the data) will not be aware of drug/placebo group. One researcher who is not involved in patients' management will be aware of Drug/Placebo group. The patients will be followed in 3rd , 14th, 30th and 90th day of treatment. The out of hospital follow-up will be by phone-follow up. 3. Setting and conduct: patients with previous medical history or spirometry compatible with COPD, presenting to emergency department with positive criteria for ECOPD (Dyspnea, increased sputum and/or purulent sputum) will be included in this study prospectively. The patients will receive either Placebo or Rosuvastatin. 4. Participants including major eligibility criteria: - Inclusion criteria: 1) hospitalized patients with past history compatible with AECOPD and 2 of following symptoms: Dyspnea, increased sputum and/or purulent sputum 2) Age > 40 - Exclusion criteria: 1) Acute coronary syndrome 2) history of statin therapy 3) endotracheal intubation 4) significant associated comorbidities (cardiac, renal or hepatic) 5) history of musculoskeletal disorders 6) history of intolerance to statins 5. Intervention: during first 24 hours of hospital admission the drug group patients will receive Rosuvastatin 40 mg (Ropixon® 40 mg) daily for 14 days. The placebo group will receive the drug with same shape and container (inert formula and starch) for same time

period. Those who will discharge before 14 days will continue treatment at home for total 14 days. All patients will receive all other current recommended treatment of AECOPD with bronchodilators, corticosteroids and antibiotics and the study will not interfere with recommended treatments for AECOPD. 6. Main outcome measures (variables): 1) Persian version COPD assessment test (CAT) in 1st 3rd and 14th day of treatment 2) modified BORG scale in 1st 3rd and 14th day of treatment 3) Arterial pulse-oximetry in 1st 3rd day of treatment 4) Arterial CO2 pressure in 1st 3rd day of treatment 5) Re-admission due to AECOPD in following 3 month 6) hospitalization period 7) ICU admission during hospital stay.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121020024N4**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

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Name of organization / entity

Tehran University Of Medical Sciences

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Recruitment status**Recruitment complete****Funding source**

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-01-30, 1395/11/11

Expected recruitment end date

2018-01-31, 1396/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

High dose Rosuvastatin as an adjunctive treatment in acute exacerbation of chronic obstructive pulmonary disease, a randomized double blind clinical trial.

Public title

High dose Rosuvastatin as an adjunctive treatment in acute exacerbation of chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

- Inclusion criteria: 1) hospitalized patients with acute exacerbation of COPD (AECOPD) according to 2 of following symptoms: Dyspnea, increased sputum and/or purulent sputum; 2) Age > 40; 3) Previous Spirometry or clinical history compatible with COPD. - Exclusion criteria: 1) Acute coronary syndrome; 2) history of statin therapy; 3) endotracheal intubation; 4) significant associated comorbidities (cardiac, renal or hepatic); 5) history of musculoskeletal disorders; 6) history of intolerance to statins.

AgeFrom **40 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **90****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 Tehran University of Medical Sciences

Street address

6th floor, Vice Chancellor for Research, Tehran University of Medical Sciences central building, Keshavarz blvd. Ghods street.

City

Tehran

Postal code**Approval date**

2017-01-16, 1395/10/27

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.1478

Health conditions studied**1****Description of health condition studied**

Chronic obstructive pulmonary disease with acute exacerbation

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with acute exacerbation, unspecified

Primary outcomes**1****Description**

in hospital mortality

Timepoint

during hospitalization

Method of measurement

monitoring of the patients' clinical status

2**Description**

Duration of hospitalization

Timepoint

during patients' hospital stay

Method of measurement

time period of hospitalization in days

3**Description**

Recurrence of acute COPD exacerbation

Timepoint

Within 3 months after taking medication

Method of measurement

Telephone follow-up

Secondary outcomes

1

Description

COPD Assessment Test (CAT) questionnaire, Persian version

Timepoint

in 1st and 3rd day after initiation of medication

Method of measurement

COPD Assessment Test (CAT) questionnaire score

2

Description

Arterial oxygen saturation of hemoglobin

Timepoint

in 1st and 3rd day of taking medication

Method of measurement

Pulse oximeter - Beurer GmbH

3

Description

Arterial PCO₂

Timepoint

in 1st and 3rd day of taking medication

Method of measurement

VL 995 blood gas analyzer

Intervention groups

1

Description

The drug group will receive Rosuvastatin tablet (Ropixon®), dose 40 mg, manufactured by Dr. ABIDI PHARMACEUTICAL LABORATORY. The patients will receive the drug, once daily (first dose on the first day of admission), for 14 days.

Category

Treatment - Drugs

2

Description

The placebo group will receive a tablet with exact shape of Rosuvastatin tablet provided by Dr. ABIDI PHARMACEUTICAL LABORATORY. The patients will receive the placebo, once daily (first dose on the first day of admission), for 14 days. The container of the drug and placebo tablets will be in same shape that the researchers, patients and clinicians could not discriminate the drug from placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamkhomeini hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Soheil Peiman

Street address

Gharib Street, End of Keshavarz blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Javad Mousavi

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Vice chancellor for research, 6th Floor, Central organization of Tehran University of Medical Sciences, Ghods street, Keshavarz blv,

City

Tehran

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, Tehran 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

Department of Internal medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr. Soheil Peiman

Position

Assistant professor

Other areas of specialty/work

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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