Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 sirometry 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) in1st 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

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Soheil Peiman

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.
Age
From **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 committe 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
Recurrencof acute COPD exacerbation
Timepoint

Within 3 months after taking meication

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 Rosuvastain 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 Rosuvastain 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.

City

Tehran

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

Street address

Vice chancellor for research, 6th Floor, Central organization of Tehran University of Medical Sciences, Ghods street, Keshavaez 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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Person responsible for scientific 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