

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of noninvasiv ventilation in hypercapnic interstitial lung diseases

Protocol summary

Study aim

Determine of Non-invasive ventilation (NIV) in patient with hypercapnic interstitial lung disease

Design

Randomized Clinical trial without blinding, with control group and sample size of 20.

Settings and conduct

The study will be done among the patients with interstitial lung diseases and hypercapnic respiratory failure attended Isfahan Khoorshid hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with Interstitial lung diseases; restrictive spirometry; honey combing in HRCT. Non-inclusion criteria: Unwillingness of the patient to use NIV; Intolerance of the patient to use NIV

Intervention groups

Interventional group :Patient with interstitial lung diseases and hyper capnia treatment with NIV and fallow for one month with 6 minute walking test . Control group:patient with interstitial lung diseases and hyper capnio treatment with conventional drugs and falow for one month with 6 minute walking test.

Main outcome variables

Quality of life; activity tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043032N1**

Registration date: **2020-04-30, 1399/02/11**

Registration timing: **retrospective**

Last update: **2020-04-30, 1399/02/11**

Update count: **0**

Registration date

2020-04-30, 1399/02/11

Registrant information

Name

Abbas Samim

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3662 0672

Email address

int.samim1358@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of noninvasiv ventilation in hypercapnic interstitial lung diseases

Public title

Non invasive ventilation in hypercapnic Interstitial lung diseases

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with Intrestitial lung diseases Restrictive pattern in pulmonary function test (PFT) Honnycombing in HRCT

Exclusion criteria:

Patient who indisposition to use niv Patient who do not tolerance niv

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization will be done using the "www.randomization.com". Randomization unit: individual

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan University of Medical Science

Street address

No.10; Mohammadi alley; at the beginning of Bagh Behesht alley; Apadana street; Esfahan

City

Esfahan

Province

Isfahan

Postal code

8165773861

Approval date

2019-11-30, 1398/09/09

Ethics committee reference number

IR.MUI.MED.REC.1398.457

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

Hypercapnic respiratory failure

ICD-10 code

J96.92

ICD-10 code description

Respiratory failure, unspecified with hypercapnia

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

Quality of life

Timepoint

At the beginning of the study and one month later

Method of measurement

SF36 questionnaire

2**Description**

Distance

Timepoint

At beginning of study and one month later

Method of measurement

6 minute walking test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Non invasive ventilation

Category

Treatment - Devices

2**Description**

Control group: usual treatment in interstitial lung disease

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Esfahan Khorshod hospital

Full name of responsible person

Abbas Samim

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjo

Street address

No.10; Mohammadi alley; at the beginning of Bagh
Behesht alley; Apadana street; Esfahan

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Province

Isfahan

Postal code

8165773861

Phone

+98 31 3632 0672

Fax**Email**

Int.samim1358@gmail.com

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Abbas Samim

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Email

Int.samim1358@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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009836320672

Email

Int.samim1358@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available