

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of noninvasiv ventilation in hypercapnic interstitial lung dieases

#### 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 Khorshid 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 fallow 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 tollerance 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**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Shaghayegh Haghjo

**Street address**

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**Fax****Email**

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**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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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant

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Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Esfahan University of Medical Sciences

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**Email**

## **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