Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of noninvasiv ventilation in hypercapnic interestitial 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 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 interestitial lung diseaes and hyper capnia treatment with NIV and fallow for one month with 6 minute walking test . Control group:patient with interestitial lung diseas 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)
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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 interestitial lung dieases

Public title
Non invasive ventilation in hypercapnic Interstitial lung diseases
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with Intrestitial lung dieases 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 Univercity of Medical Science
Street address
No.10; Mohammadi alley; at the beginning of Bagh Behesht alley; Apadana street; Esfahan
City
Esfahan
Province
Isfehan
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 biggining 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 interastitial 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Haghjo
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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 updating data

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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