Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of vitamin D replacement on patients with pulmonary hypertension and vitamin D deficiency

Protocol summary

Summary

Pulmonary Hypertension is a life-threatening disease in which with progressive increase in pulmonary vascular resistance patients come down with Heart failure and progressive decreasing in cardiac out put and this condition will end up to death.There are several kind of medication to control the disease,but in the course of disease may patients affected by other condition that will deteriorate the condition.one of these conditions is vitamin D deficiency, in our research we will evaluate the effect of vitamin D replacement therapy on 36 patients of Pulmonary Hypertension, who have suffered of vitamin D deficiency.So patients with Vitamin D deficiency and Pulmonary Hypertension in age 20-65 years old will be included in our study and ones who deny our trial or experience some medical complications will be excluded.,we will start replacement therapy by Vitamin D and calcium and after normalization of it's plasma level we will compare exercise capacity,pulmonary artery pressure and plasma level of Pro-Brain natriuretic peptide in the patients with pre treatment's variables of their own.and finally by analyzing the data we are going to observe the effect of vitamin D deficiency and it's treatment on patient with pulmonary Hypertension.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091713828N3**
Registration date: **2013-11-23, 1392/09/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-23, 1392/09/02

Registrant information

Name
Ahmad Mirdamadi
Name of organization / entity
Islamic Azad university ,Najafabad branch
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Iran (Islamic Republic of)
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drsamirdamadi@pmd.iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University,Najafabad branch

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D replacement on patients with pulmonary hypertension and vitamin D deficiency

Public title

Vitamin D replacement therapy in patients with pulmonary Hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: History of Pulmonary Hypertension(Mean PAP more than 25mmHg by cardiac Catheterization);Presence of Vitamin D deficiency;Not using Vitamin D supplements before

intervention;Patient's content Exclusion Criteria: Adverse reaction of medication during the intervention;Failing of patient to keep on the trial

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Medical University

Street address

Hezar jarib street-azadi square

City

Isafahan

Postal code

Approval date

2013-10-02, 1392/07/10

Ethics committee reference number

492030

Health conditions studied

1

Description of health condition studied

Pulmonary Hypertention

ICD-10 code

126-128

ICD-10 code description

Pulmonary heart disease and diseases of pulmonary circulation

Primary outcomes

1

Description

6 Minute Walk Test

Timepoint

Before intervention and also after normalization of plasma level of Vitamin D

Method of measurement

This test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes

2

Description

Pro-BNP

Timepoint

Before intervention and also after normalization of plasma level of Vitamin D

Method of measurement

Chimiluminescence

3

Description

Pulmonary Artery Pressure

Timepoint

Before intervention and also after normalization of plasma level of Vitamin D

Method of measurement

By Echocardiography and if need Right Heart catheterization

Secondary outcomes

1

Description

Plasma level of Vitamin D

Timepoint

Before intervention and 3 months after treatment and if need 6 months later

Method of measurement

Chimiluminescence

Intervention groups

1

Description

In this study 36 known case of pulmonary hypertension that had confirmed by Right Heart Catheterization will enter the study.Entering the study is based on patient's content and presence of Vitamin D deficiency(plasma level of Vitamin less than 30 ng/ml).In the first step demographic information like age,sex and past history of Heart disease will be recorded.and then 6MWT,plasma level of Pro-BNP and Pulmonary artery pressure will be added.In the trial course 50.000 IU of Vitamin D will be prescribed weekly in addition to 1 pill of Calcicare(contains of 200 mg magnesium,8 mg zinc and 400 IU of vitamin D).After 3 months plasma level of vitamin D will be measured and if it is not in normal range the second

course of treatment will be carried out. after normalization of plasma level of vitamin D reevaluation of patients will be started by measuring the 6MWT,plasma level of Pro-BNP and Pulmonary artery pressure. At the end variables will be entered the analyzing software to analyze the data.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Shariati. Hospital

Full name of responsible person

Dr. Mirdamadi

Street address

Shariati street

City

Isfahan

2

Recruitment center

Name of recruitment center

Isfahan Hospital

Full name of responsible person

Dr. Mirdamadi

Street address

Sheikhbahei street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University,Najafabad branch,Isfahan

Full name of responsible person

Dr.Mirdamadi

Street address

Najafabad Islamic Azad University، Daneshgah blv

City

Najafabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University,Najafabad branch,Isfahan

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University of Najafabad

Full name of responsible person

Dr. Mirdamadi

Position

Assistant Professor of Medical School/Cardiologist,Fellowship of Echocardiography

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University of Najafabad

Full name of responsible person

Dr. Mirdamadi

Position

Assistant Professor of Medical School/Cardiologist,Fellowship of Echocardiography

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