A nutrition and lifestyle intervention in patients with PuLmonary Arterial Hypertension: effect on quality of life

Published: 30-07-2019
Last updated: 11-04-2024

To explore the effect of a nutrition and lifestyle intervention on quality of life for patients suffering from PuLmonary Arterial Hypertension.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON48646

Source
ToetsingOnline

Brief title
UPHILL

Condition

- Heart failures
- Pulmonary vascular disorders

Synonym
high blood pressure in the pulmonary arteriole, Pumonary Arterial Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: PH fonds

Intervention

Keyword: Lifestyle, Nutrition, Pulmonary Hypertension

Outcome measures

Primary outcome

To explore the effect of a nutrition and lifestyle intervention for

PAH-patients on quality of life.

Secondary outcome

- Perform a systematic analyses of nutritional status. Is nutritional status

associated with clinical worsening or RV function in PAH?

- Determine the effect of nutritional education alone, and the additional

effect of a nutritional intervention in PAH.

- Determine which nutritional intervention is most effective. Which diet is

associated with the largest improvement in quality of life and best compliance

in PAH?

Study description

Background summary

Nutrition and lifestyle interventions are currently not implanted in usual clinical care of PAH-patients. Mainly because there is little known on the relation between pathology, nutrition and lifestyle. Patients who suffer from Pulmonary Arterial Hypertension feel insecure about their nutrition and lifestyle. We hypothesize that an intervention on nutrition and lifestyle can improve the patients* quality of life.

Study objective

To explore the effect of a nutrition and lifestyle intervention on quality of life for patients suffering from PuLmonary Arterial Hypertension.

Study design

Investigator initiated intervention study.

Intervention

Every subject will have the option to wear a Fitbit during this study, and than has to wear it day and night, during the entire study. With the Fitbit we want to track the general wellbeing: daily exercise, heartrate and the sleeping pattern. Fitbit has an secured research platform that collects data from internet connected devices: Fitabase. This cloud-based software is fully hosted, keeps data private and has been used in over 400 studies. The subjects will be randomly assigned to the intervention and control group. Subsequently, patients in the intervention group will be randomly assigned to the MedDASH diet or MedDASHfat diet.

First, we will perform baseline measurements in the study and control group to determine the nutritional status.

Subsequently, patients of the intervention group will receive nutritional education. In 8 plenary masterclasses information is provided on the use of sugar, fluid, salt, herbs, amino acids, fatty acids, vegetables, alcohol, product labels and medication interactions with nutrition. The masterclasses, with a duration of three hours for every session, will be given in small groups (maximum of ten per group) and the patients will receive homework with nutrition and lifestyle assignments. Two weeks after the last masterclass the whole study group will participate in a cooking masterclass on location, to implement the obtained knowledge.

After the nutritional education, the subjects of the intervention group will be randomly assigned to a MedDASH diet or a MedDASHfat diet. The MedDASH diet is comprised of 55% carbohydrates, 25% amino acids, 20% fatty acids, whereas the MedDASHfat diet is comprised of 10% carbohydrates, 25% amino acids, 65% fatty acids. Both groups will receive a list of products they can consume daily, daily menu examples and precepts for the diet and lifestyle (for example: only eat carbohydrates once a day, don*t use blue light after 10 p.m., make a list before you go grocery shopping). After 3 months of diet, efficacy is tested by comparing quality of life, RV function, exercise capacity and general well-being between the 2 diets and the control group. After 6 months, compliance is analysed.

Study burden and risks

The burden for the patient exists of 12 extra visits to the hospital and contact moments, over a period of 11 months, as well compliance to the diet and lifestyle. The radiation risk form the DEXAscan is minimal, with 0,05 mSV in

the total study There is a minimum risk in participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnoses of idiopathic PAH, hereditary PAH or drug related PAH
Age between 18 and 80
NYHA II or III and stable for at least three months, measured with 6MWT <10% differnce
Self-sufficient and/or compliance from partner and/or family
Creatinine > 30 ml/min
Able to understand and willing to sign the Informed Consent Form

Exclusion criteria

Pregnant subjects
Fat percentage < 10% > 55%
One or more of the following comorbidities: diabetes mellitus type one or two, clinical relevant hypothyroid
Known history of noncompliance considering therapies

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2019
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	30-07-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL66484.029.18