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A pilot study on the effect of niacin on pulmonary arterial pressure

Submission date
27/03/2015

Recruitment status
No longer recruiting

Registration date
23/04/2015

Overall study status
Completed

Last Edited
17/05/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to determine whether the drug niacin can help patients with high blood pressure in their lung arteries, also called pulmonary hypertension. This is a study specifically for volunteers who do NOT have high blood pressure in the lung's arteries. This study is important because the medications that are used to treat pulmonary arterial hypertension are very limited. Any new medications that might work to lower pulmonary arterial blood pressure would be very helpful for these patients.

Who can participate?
Patients aged over 18 with a tricuspid regurgitation jet velocity over 2.7 m/s on an inpatient echocardiogram during their current hospital stay.

What does the study involve?
First, you will get an echocardiogram, which is a non-invasive test that uses ultrasound waves to evaluate a picture of the heart. You will then be randomly allocated to take one of three different pills: niacin 100 mg pill, niacin 500 mg pill, or a sugar pill (a placebo). Neither you nor the investigator will know what group you in. One hour after taking your pill, you will get a second ultrasound of your heart.

What are the possible benefits and risks of participating?
We do not expect for you to have any direct medical benefits from participating in this study, but we hope that the information we gain will help patients with pulmonary arterial hypertension. You will be compensated with a $20 gift card for your participation. This study will not interfere with the evaluation and treatment of the condition that brought you to the hospital. It will not add any cost to your stay and will not delay your discharge. Risks and side effects related to the study include flushing of your skin after taking niacin. There may also be side effects that we cannot predict. Other drugs will be given to make side effects that occur less serious and less uncomfortable.

Where is the study run from?
MedStar Georgetown University Hospital (USA).

When is the study starting and how long is it expected to run for?
March 2013 to April 2014.

Who is funding the study?
Folger Grant for Cardiovascular Prevention.

Who is the main contact?
Martin McNamara

Contact information

Type(s)
Public

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Protocol serial number
IIS12067

Study information

Scientific Title
A pilot randomized double-blinded single-dose provocation study on the effect of niacin on pulmonary arterial pressure

Study objectives
We hypothesized that immediate-release niacin would reduce right ventricular systolic pressure in patients with pulmonary hypertension via the release of vasodilating prostaglandins in a randomized, double-blinded, single-dose provocation study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) of Georgetown University Hospital, 10/05/2011, study number 2012-067

Study design
Randomized double-blinded single-dose provocation study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pulmonary hypertension

Interventions
Subjects were randomized in a 1:2:2 ratio to receive a single dose of either placebo, niacin 100 mg or niacin 500 mg, respectively. TR jet velocities were measured immediately before, and one-hour post dose, corresponding to peak niacin absorption and prostaglandin release.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Niacin

Primary outcome(s)
Change in mean tricuspid regurgitation jet velocity measured in meters/second one hour after study drug administration.

Key secondary outcome(s))
Change in maximum tricuspid regurgitation jet velocity measured in meters/second one hour after study drug administration.

Completion date
12/06/2014

Eligibility

Key inclusion criteria
1. Over the age of 18
2. Display a tricuspid regurgitation jet velocity over 2.7 m/s on an inpatient echocardiogram during their current hospital stay

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
49

Key exclusion criteria
1. Inability to provide written informed consent
2. Known pulmonary vascular disease
3. Known intolerance to niacin or current treatment with niacin
4. Current treatment with a non-steroidal anti-inflammatory drug (NSAID)
5. Known liver disease (AST/ALT > 3x the upper limit of normal)
6. Patients currently on ventilator support or using a bi-level positive airway pressure (BiPAP) device

Date of first enrolment
25/03/2013

Date of final enrolment
14/04/2014

Locations

Countries of recruitment
United States of America

Study participating centre
MedStar Georgetown University Hospital
United States of America
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Sponsor information

Organisation
Georgetown University Institutional Review Board

ROR
https://ror.org/05vzafd60

Funder(s)

Funder type
Other

Funder Name
Folger Grant for Cardiovascular Prevention

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/11/2015		Yes	No