ARA290 and the ventilatory response to hypoxia and pain responses in healthy volunteers.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23515

Source
Nationaal Trial Register

Brief title
ARA study

Health condition

Hypoxia; Hypoxic Pulmonary Vasoconstriction; Hypoxic Ventilatory Response.

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

1. Hypoxic Ventilatory Response (HVR);

2. Pulmonary Artery Pressure (PAP).

Secondary outcome

1. Systolic and diastolic cardiac functions;

2. Vital and ventilatory parameters;

3. Pain thresholds under hypoxia.

Study description

Background summary

Epo seems to have and effect on hypoxic sensing in the carotid body and might effect the sensing in the pulmonary vascular tree. We want to investigate if this is detectable and what an Epo analog like ARA290 does on the HVR and PAP.

Study objective

Are there effects of ARA290 and Epo on the ventilatory response to hypoxia. Are there effects of ARA290 and Epo on the gradient over the tricuspid valve during hypoxia a an estimation of the pulmonary artery pressure (PAPA). Does ARA290 and/or Epo affect the pain responses?

Study design

T = 0 min arrival in the laboratory;

T = 15 min: insertion of IV and arterial line and drawing of a blood sample for Hemoglobin concentration measurement;

T = 30 min baseline measurements PAIN 10 min
ECHO 40 min RESPIRATION 40 min;

T = 120 min TREATMENT injection (ARA290, Epo, Placebo);

T = 150 min effect measurements PAIN 10 min
ECHO 40 min RESPIRATION 40 min;

T = 240 min End of Study.

Intervention

Healthy volunteers will each be seen for three sessions, with 2 weeks in between. Hypoxia will be induced using the computer driven Dynamic End-Tidal Forcing (DEF) Technique; end-tidal oxygen concentrations will be lowered to 5.8 kPa (about 45 mmHg) to reach an oxygen saturation of 80 ± 2 %, whereas the PCO2 level remains constant (end-tidal concentration is rest endtidal PCO2 + 2-3 mmHg). The subjects will breathe in and out through a face mask with a pneumotachograph to measure ventilation on a breath-to-breath basis. The maximum pressure difference across the tricuspid valve (ΔP max) will be measured using Doppler echocardiography. An arterial line will provide information about the arterial blood gas and BP. Each time one substance, either NaCl 0,9%, Erythropoietin or ARA290, will be administered by intravenous injection. Cardiac output will be measured with the Vigileo monitor (Edwards Lifesciences) and by cross sectional echocardiography, using the diameter of the left ventricular outflow tract, with the image frozen in midsystole, to calculate the cross sectional area, assuming a circular profile. We will measure aortic blood velocity by continuous wave Doppler.

Contacts

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Eligibility criteria

Inclusion criteria

The major inclusion criteria is that the subject has echo evidence of tricuspid regurgitation during systole, which is not clinically relevant but in fact can be demonstrated in most normal individuals.

Exclusion criteria

1. Obesity (BMI > 35);

2. Presence of medical disease (heart-, lung-, liver-, kidney-, neurologic disease; diabetes m.; pyrosis; diaphragmatic hernia);

3. Presence of psychiatric disease;

4. History of chronic alcohol or illicit drug use;

5. Allergy to study medications. For females we require the use of oral contraceptives.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2011
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-11-2011
Application type:	First submission

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
NTR-new	NL2983
NTR-old	NTR3131
Other	METC LUMC / CCMO : p10144 / NL32314.058.10;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A