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

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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...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON23515

**Bron**
NTR

**Verkorte titel**
ARA study

**Aandoening**

Hypoxia; Hypoxic Pulmonary Vasoconstriction; Hypoxic Ventilatory Response.

### Ondersteuning

**Primaire sponsor:** Leiden University Medical Center (LUMC)
**Overige ondersteuning:** Leiden University Medical Center (LUMC)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

1. Hypoxic Ventilatory Response (HVR);<br>
2. Pulmonary Artery Pressure (PAP).

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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?

### Onderzoeksopzet

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.

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-10-2011 |
| Aantal proefpersonen: | 16 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 01-11-2011 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL2983 |
| NTR-old | NTR3131 |
| Ander register | METC LUMC / CCMO : p10144 / NL32314.058.10; |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A