Glucose II study.

No registrations found.

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

Summary

ID

NL-OMON20631

Source
Nationaal Trial Register

Brief title
Glucose II

Health condition

hypoxia, pulmonary hypertension, COPD, diabetes,

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

1. Ventilatory response: We will monitor ventilation continuously and afterwards analyze these data based on acute response as well as non linear modeling;

2. Pulmonary arterial pressure will be estimated using the tricuspid valve maximum gradient, which is a good estimate of the systolic pulmonary arterial pressure, using echocardiography. We will monitor the PAP every minute for the first 20 minutes and thereafter every 5 minutes.

Secondary outcome

Vital and echocardiographic parameters.

Study description

Background summary

The HVR and HPV are effected by several metabolic processes. In this study we want to investigate whether these reflexes are under direct influence of glucose levels and what the magnitude of the effect is.

Study objective

Hyperglycaemia alters the sustained hypoxic pulmonary vasoconstriction (HPV) and the hypoxic ventilatory response (HVR).

Study design

Every minute for the first 20 minutes, hereafter every 5 minutes for the remaining 40 minutes.

Intervention

Crossover trial, with randomly a hyperglycaemic (15 mmol/l) hypoxic episode of 60 minutes and a normoglycaemic hypoxic episode of 60 minutes. Hyperglycaemia accomplished according the glucose clamp technique of Defronzo et al. Two episodes at least to weeks apart.

Contacts

Public
Department of Anesthesiology
LUMC, P5-Q
Rob Lindeman
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301
Scientific
Department of Anesthesiology
LUMC, P5-Q

Rob Lindeman
Leiden 2300 RC
The Netherlands
+31 (0)71 5262301

Eligibility criteria

Inclusion criteria

Healthy volunteers aged 18-45 with 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 > 30);

2. Presence of medical disease: heart-, lung-, liver-, kidney- and lung disease; diabetes;

3. Presence of psychiatric disease;

4. History of chronic alcohol or drug use;

5. Possibility of pregnancy;

6. Lactation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-01-2012
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	NL3088
NTR-old	NTR3236
Other	METC LUMC / CCMO : P11.058 / NL35083.058.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A