

# Influence of hyperglycaemia and sustained hypoxia on the hypoxic ventilatory response and the hypoxic pulmonary vasoconstriction.

Published: 04-07-2011

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In this study we want to investigate the effects of sustained hyperglycaemia and hypoxia on the hypoxic pulmonary vasoconstriction and hypoxic ventilatory response

|                              |                        |
|------------------------------|------------------------|
| <b>Ethical review</b>        | Approved WMO           |
| <b>Status</b>                | Recruitment stopped    |
| <b>Health condition type</b> | Diabetic complications |
| <b>Study type</b>            | Interventional         |

## Summary

### ID

NL-OMON35915

### Source

ToetsingOnline

### Brief title

Glucose II

### Condition

- Diabetic complications
- Pulmonary vascular disorders

### Synonym

diabetes

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** hyperglycaemia, hypoxia, pulmonary pressure, ventilation

## Outcome measures

### Primary outcome

systolic PAP

HVR

HVD

### Secondary outcome

nvt

## Study description

### Background summary

Hypoxia and hyperglycaemia are important factors in the development of pulmonary diseases. The exact mechanism of the human reaction to hypoxia is unclear. It is clear however that metabolic factors are of great importance.

### Study objective

In this study we want to investigate the effects of sustained hyperglycaemia and hypoxia on the hypoxic pulmonary vasoconstriction and hypoxic ventilatory response

### Study design

Double blinded randomized trial, the subjects will be subjected to the protocol twice (normoglycaemia and hyperglycaemia)

### Intervention

hypoxia  
hyperglycaemia

## Study burden and risks

headache during hypoxia sometimes occurs, which is treated with paracetamol  
a bruise may occur on the spot of the iv  
hyperglycaemia is tolerated well and has no side effects after such a short period

## Contacts

### Public

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2333 ZA, Leiden  
NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

The major inclusion criteria are that the subject is healthy and 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

Obesity (BMI > 30), Presence of medical disease: heart-, lung-, liver-, kidneydisease; diabetes, Presence of psychiatric disease, History of chronic alcohol or drug use, Possibility of pregnancy, Lactation

## Study design

### Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Interventional                |
| Intervention model: | Parallel                      |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Double blinded (masking used) |
| Control:            | Placebo                       |
| Primary purpose:    | Other                         |

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 20-01-2012          |
| Enrollment:               | 13                  |
| Type:                     | Actual              |

## Ethics review

|                    |                                     |
|--------------------|-------------------------------------|
| Approved WMO       |                                     |
| Date:              | 04-07-2011                          |
| Application type:  | First submission                    |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
|                    | metc-ldd@lumc.nl                    |

## 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     | NL36320.058.11 |