

# Nocturnal Free Fatty Acids. Measurements in obese and lean subjects and the effect of $\alpha$ -blockage on pulsatile release.

No registrations found.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Positive opinion           |
| <b>Status</b>                | Pending                    |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON21331

### Source

NTR

### Brief title

NFFA

### Health condition

free fatty acid release

vrije vetzuur afgifte

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC), Department of Endocrinology and Metabolism

P.O. Box 22660

1100 DD

Amsterdam

The Netherlands

+31 (0)20 5669111

**Source(s) of monetary or material Support:** fund=initiator=sponsor

## Intervention

## Outcome measures

### Primary outcome

- Percent and/or absolute changes in nocturnal FFA levels with or without  $\alpha$ -blockage.

### Secondary outcome

- Difference in nocturnal FFA levels between lean and obese subjects

## Study description

### Background summary

It has been convincingly demonstrated that free fatty acids (FFA) play a key role in the induction of obesity-induced insulin resistance. The higher plasma levels of FFA originate from adipocytes which show higher rates of lipolysis in insulin stimulated states, i.e. insulin resistance of adipose tissue. The release of FFA is pulsatile and show a circadian rhythm and is thereby in part controlled by the central nervous system. Whether this pulsatility or rhythm is disturbed in insulin resistant subjects is not known. In a dog model FFA levels can be lowered by blocking the  $\alpha$ -receptor present on the adipocyt, thereby decreasing the influence of the central nervous system on FFA release. In this study we aim to translate these findings to obese insulin resistant and lean insulin sensitive humans.

### Study objective

Nocturnal FFA levels are higher in obese insulin resistant subjects and are less sensitive to the FFA lowering effects of a  $\alpha$ -receptor blocker.

### Study design

N/A

### Intervention

Propranolol infusion

## Contacts

### Public

Academic Medical Center (AMC) <br>  
Department of Endocrinology and Metabolism <br>  
P.O. Box 22660<br> 1100 DD  
B.A.M. Weijer, de  
Meibergdreef 9 (F5-177)

Amsterdam 1105 AZ  
The Netherlands  
+31 (0)20 5666849

### Scientific

Academic Medical Center (AMC) <br>  
Department of Endocrinology and Metabolism <br>  
P.O. Box 22660<br> 1100 DD  
B.A.M. Weijer, de  
Meibergdreef 9 (F5-177)

Amsterdam 1105 AZ  
The Netherlands  
+31 (0)20 5666849

## Eligibility criteria

### Inclusion criteria

1. Male obese subjects (BMI > 30 kg/m<sup>2</sup>) and healthy lean controls (BMI 20 > 25 kg/m<sup>2</sup>)
2. Age 20 – 50 years
3. Stable weight 3 months prior to study inclusion
4. Caucasian
5. Written informed consent

### Exclusion criteria

1. Any chronic medical condition or use of any medication

2. Asthma and bronchospastic COPD
3. Tobacco use
4. Alcohol abuse (>3/day)
5. Frequent intensive exercise (>2 week)
6. Familial lipid disorders, renal insufficiency (creatinine > 150 umol/L) , elevated liver enzymes (> 2 times), hypertension
7. Hypotension (BP < 100/60 mmHg), bradycardia (HR < 60min)
8. Unwilling or unable to provide informed consent
9. First degree family members with diabetes
10. Abnormal day/night rhythm (shiftworkers etc)
11. Blood donation in the past three months

## Study design

### Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Observational non invasive    |
| Intervention model: | Other                         |
| Allocation:         | Non controlled trial          |
| Masking:            | Single blinded (masking used) |
| Control:            | N/A , unknown                 |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-12-2008  |
| Enrollment:               | 20          |
| Type:                     | Anticipated |

## Ethics review

Positive opinion

Date: 19-11-2008

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  | NL1481                             |
| NTR-old  | NTR1549                            |
| Other    | : 08/282                           |
| ISRCTN   | ISRCTN wordt niet meer aangevraagd |

## Study results

### Summary results

N/A