Pilot Study for a Randomized Clinical Trial to Study Ketogenesis and Glucose-Dependent Insulin Secretion Methodologies in Healthy Male Subjects

Published: 03-03-2010
Last updated: 03-05-2024

The purpose of the study is to investigate ketogenesis and glucose dependant insulin secretion methodologies. In addition, blood samples will be collected to assess the feasibility of performing study procedures and sample processing.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34910

Source
ToetsingOnline

Brief title
ketogenesis and glucose -dependent insulin secretion methods pilot study

Condition

- Other condition

Synonym
anti-obesity

Health condition

anti-obesity

Research involving

Human

Sponsors and support

Primary sponsor: PRA International EDS
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Glucose, Ketogenesis, methods

Outcome measures

Primary outcome

To evaluate the logistics, feasibility, and safety of procedures for a clinical

trial that will assess methodologies used to evaluate ketogenesis and

glucose-dependent insulin secretion.

Secondary outcome

N/A

Study description

Background summary

Pilot Study to assess Ketogenesis and Glucose-Dependent Insulin Secretion Methodologies in Healthy Male Subjects

Study objective

The purpose of the study is to investigate ketogenesis and glucose dependant insulin secretion methodologies. In addition, blood samples will be collected to assess the feasibility of performing study procedures and sample processing.

Study design

A randomized pilot study for ketogenesis and glucose-dependent insulin secretion methodologies in two healthy male obese subjects.

Procedures and assessments:

Screening and follow-up:
Clinical laboratory, bloodpressure and vital signs, physical examination,
12-lead ECG, drug screen
Only by screening:
medical history, height, weight, HBsAG, anti HCV and anti-HIV.

Observation period:
-17 up to approx 9 hours after dosing

Study burden and risks

Procedures: pain, light bleeding, heamatoma and possibly an infection.

Contacts

Public
PRA International EDS

Stationsweg 163
9471 GP Zuidlaren
Nederland
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

18-45 years,
BMI 27-35 kg/m2 (inclusive)

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/Aids. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters blood in the 10 months preceding the start of the study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2010
Enrollment:	3
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL31792.056.10