Het effect van fenretinide op insulinegevoeligheid.

No registrations found.

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

Summary

ID

NL-OMON25232

Source
Nationaal Trial Register

Brief title
FEN

Health condition

Obesity
Metabolic syndrome X
Insulin resistance
Fatty liver

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: Academic Medical Center (AMC)

Intervention

Outcome measures

Primary outcome

Changes in hepatic and peripheral insulin sensitivity.

Secondary outcome

1. Liver steatosis;

2. Plasma retinol and RBP4 levels;

3. Subcutaneous adipose tissue: Concentrations of RBP4 and key proteins involved in insulin signaling levels;

4. Plasma HPR and its metabolites (MPR, 4-oxo-HPR) levels;

5. Resting energy expenditure (REE) and body fat composition;

6. Glucoregulatory hormones, adipokines and markers of inflammation;

7. Safety and tolerability of HPR/LXS.

Study description

Background summary

The prevalence of type 2 diabetes mellitus (T2DM) and obesity is increasing. Recent studies have provided evidence that retinol binding protein 4 (RBP4) is involved in the induction of insulin resistance (IR). Fenretinide is a synthetic retinoid found to lower RBP4 levels. Preliminary data show that it might improve insulin sensitivity, making it a potential new therapy for IR and T2DM. The aim of this study is assess the effects of fenretinide on hepatic and peripheral insulin sensitivity in obese, insulin resistant subjects.

Study objective

Fenretinide improves insulin sensitivity in obese, insulin resistant subjects.

Study design

Baseline, days 7, 28, 58 and 88 of treatment; 14 days after last drug administration.

Intervention

Fenretinide 154 mg QD for 90 days. The control group will receive a placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Post menopausal female;

2. Age 40-65 years;

3. BMI ≥ 30 kg • m-2;

4. HOMA-IR ≥ 2.7;

5. Signed informed consent.

Exclusion criteria

1. T2DM treated with medication other than metformin or sulfonylurea derivates;

2. Any medical condition except for glucose intolerance, T2DM, hypertension and secondary dyslipidemia;

3. Prolonged PTT/aPTT or thrombocytopenia;

4. Retinol levels of < 1.8 uM.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2012
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-07-2012
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	NL3304
NTR-old	NTR3502
Other	METC AMC : 12/047
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A