Can the use of the PPAR-gamma agonist rosiglitazon reverse the abnormal distribution of fat, as well as disturbances in glucose and lipid metabolism in HIV-associated lipodystrophy syndrome?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25981

Source
Nationaal Trial Register

Brief title
Rosi-trial

Health condition

HIV+ patients, with lipodystrophy (based on fat distribution disturbances), not using d4T nor a protease inhibitor.

Sponsors and support

Primary sponsor: Academic medical centre, Dept of endocrinology and metabolism, F5-170, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands
Source(s) of monetary or material Support: Glaxo Smith Kline (medication only)
Prof.dr. H.P. Sauerwein
Academic medical centre, Dept of endocrinology and metabolism, F5-170, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

1. Insulin sensitivity at the level of glucose production by liver, glucose uptake by muscle+fat and lipolysis. This will be measured by a hyperinsulinaemic clamp using stabile isotopes (d2-glucose and D5-glycerol) and by performing muscle biopsies at baseline and after 4 months;

2. Fat distribution by a DEXA- and a CT-scan at baseline and after 4 months.

Secondary outcome

1. Lipid levels;

2. Glucoregulatory hormones;

3. Adipocytokines;

4. Liver enzymes;

5. Waist-hip ratio.

Study description

Background summary

This placebo controlled studie investigates the effects of Rosiglitazon on insulin sensitivity at central and peripheral level and on fat distribution in patients with HIV-lipodystrophy, who are not using d4T nor a protease inhibitor.

Study objective

Rosiglitazone results in an improvement in insulin sensitivity at the level of the liver as well as peripherally. In addition disturbances in fat distribution could improve, especially in this specific group of patients, who do not use d4T nor a protease inhibitor, which are known to cause lipodystrophy.

Study design

N/A

Intervention

Patients will receive either Rosiglitazon 8 mg daily (2/3) or placebo (1/3) during 4 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male;

2. age>18 years;

3. documented HIV-1 infection;

4. HIV-RNA<50 copies/ml;

5. clinical evidence of lipodystrophy;

6. >36 weeks no use of a protease inhibitor;

7. > 24 no use of d4T, >12 weeks on a stabile regimen.

Exclusion criteria

1. Active hepatitis;

2. ALAT/ASAT>2.5x above normal level;

3. total bilirubin 2.5x above normal level;

4. lactate 2.5x above normal level;

5. anemia;

6. use of medication influencing metabolism/ blood clotting.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2003
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	04-11-2005
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	NL477
NTR-old	NTR518
Other	: N/A
ISRCTN	ISRCTN78808170

Study results

Summary results
N/A