

# 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.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25981

### Source

NTR

### 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

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## 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 stable 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

### Public

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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 stable 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