

# Can the use of the Peroxisome Proliferator-Activated Receptor (PPAR)-gamma agonist rosiglitazone reverse the abnormal distribution of fat, as well as disturbances in glucose and lipid metabolism in Human Immunodeficiency Virus (HIV)-associated lipodystrophy syndrome?

<b>Submission date</b> 26/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/10/2017	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**

N/A

## **Study information**

### **Scientific Title**

Can the use of the Peroxisome Proliferator-Activated Receptor (PPAR)-gamma agonist rosiglitazone reverse the abnormal distribution of fat, as well as disturbances in glucose and lipid metabolism in Human Immunodeficiency Virus (HIV)-associated lipodystrophy syndrome? A randomised controlled trial

### **Acronym**

Rosi-trial

### **Study objectives**

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.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approval received from the Medical ethical committee of the Academical Medical Centre in Amsterdam on the 2nd October 2002 (ref: MEC 02/126).

### **Study design**

Randomised, placebo controlled, parallel group, double blinded trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Human Immunodeficiency Virus (HIV)-associated lipodystrophy syndrome

### **Interventions**

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

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Rosiglitazone

**Primary outcome(s)**

1. Insulin sensitivity at the level of glucose production by liver, glucose uptake by muscle and 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 four months
2. Fat distribution by a Dual Energy X-ray Absorptiometry (DEXA)- and a Computed Tomography (CT)-scan at baseline and after four months

**Key secondary outcome(s)**

1. Lipid levels
2. Glucoregulatory hormones
3. Adipocytokines
4. Liver enzymes
5. Waist-hip ratio

**Completion date**

01/08/2006

**Eligibility****Key inclusion criteria**

1. Male
2. Aged more than 18 years
3. Documented HIV-1 infection
4. HIV-Ribonucleic Acid (RNA) less than 50 copies/ml
5. Clinical evidence of lipodystrophy
6. More than 36 weeks no use of a protease inhibitor
7. More than 24 weeks no use of d4T
8. More than 12 weeks on a stable regimen

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Male

**Key exclusion criteria**

1. Active hepatitis
2. Alanine aminotransferase (ALAT)/Aspartate aminotransferase (ASAT) more than 2.5 x above normal level
3. Total bilirubin 2.5 x above normal level
4. Lactate 2.5 x above normal level

- 5. Anaemia
- 6. Use of medication influencing metabolism/blood clotting

**Date of first enrolment**

03/11/2003

**Date of final enrolment**

01/08/2006

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Academic Medical Centre (AMC)

Amsterdam

Netherlands

1100 DD

## Sponsor information

**Organisation**

Academic Medical Centre (AMC) (The Netherlands)

**ROR**

<https://ror.org/03t4gr691>

## Funder(s)

**Funder type**

Industry

**Funder Name**

GlaxoSmithKline (The Netherlands)

**Alternative Name(s)**

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

**Funding Body Type**

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United Kingdom

## Funder Name

Academic Medical Centre (AMC) (The Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2009		Yes	No