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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?

Submission date
26/02/2007

Registration date
26/02/2007

Last Edited
03/10/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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 stabile 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

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

Overall study start date
03/11/2003

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 stabile regimen

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
15

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)

Sponsor details

Department of Endocrinology and Metabolism
P.O. Box 22660
Amsterdam
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (The Netherlands)

Alternative Name(s)
GlaxoSmithKline plc., GSK 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2009		Yes	No