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Lipodystrophy in human immunodeficiency virus-infected patients: a randomised, open-label study with rosiglitazone and metformin

Submission date	Recruitment status	[_] Prospectively registered
28/04/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/10/2017	Infections and Infestations	

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
02/238

Study information

Scientific Title
Lipodystrophy in human immunodeficiency virus-infected patients: a randomised, open-label study with rosiglitazone and metformin

Study objectives
Rosiglitazone and metformin improve body fat distribution,
insulin sensitivity and cardiovascular risk indices in Human Immunodeficiency Virus (HIV)-infected patients with lipodystrophy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human Immunodeficiency Virus (HIV)

Interventions
Rosiglitazone versus metformin

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rosiglitazone and metformin

Primary outcome(s)
The area under the curve for insulin after the oral glucose tolerance test.

Key secondary outcome(s))
Subcutaneous and visceral abdominal fat by single-slice Computed Tomography (CT) scan, fasting lipid profile and ultrasound assessment of endothelial function (flow-mediated vasodilation).

Completion date
31/08/2004

Eligibility

Key inclusion criteria

HIV-Ribonucleic Acid (RNA) values less than 10,000 copies/ml, the presence of lipodystrophy, and treatment with Highly Active Anti-Retroviral Therapy (HAART) for at least 18 months with no changes in the treatment regimen during six months prior to inclusion.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. The presence of opportunistic infectious disease or malignancies, renal-, thyroid- and/or liver disease
2. Body Mass Index (BMI) more than 30 kg/m^2
3. Fasting plasma glucose more than 7 mmol/l
4. Triglycerides more than 10 mmol/l and/or total cholesterol more than 8 mmol/l
5. Alcohol intake more than three units (36 g) per day

Date of first enrolment
01/03/2003

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Department of Nephrology
Leiden
Netherlands
3584 CX

Sponsor information

Organisation
GlaxoSmithKline (The Netherlands)

ROR
https://ror.org/05atcw115

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

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

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?
Results article	results	06/09/2005		Yes	No