

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

Submission date 28/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/10/2017	Condition category 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
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

Primary study design

Interventional

Study design

Randomised controlled trial

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/m²
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