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

Submission date 28/04/2005	Recruitment status No longer recruiting	[_] Pro: [_] Pro
Registration date 10/06/2005	Overall study status Completed	[_] Stat [X] Res
Last Edited 03/10/2017	Condition category Infections and Infestations	[_] Indi

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 02/238

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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

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Treatment

Participant information sheet

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 measure

The area under the curve for insulin after the oral glucose tolerance test.

Secondary outcome measures

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

Overall study start date

01/03/2003

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

Age group Adult

Lower age limit 18 Years

Sex

Both

Target number of participants 39

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)

Sponsor details Huis ter Heideweg 62 Zeist Netherlands 3705 LZ

Sponsor type Industry

ROR https://ror.org/05atcw115

Funder(s)

Funder type Industry

Funder Name GlaxoSmithKline

Alternative Name(s) GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type Government organisation **Funding Body Subtype** For-profit companies (industry)

Location United Kingdom

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	06/09/2005		Yes	No