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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/06/2005	**Overall study status** Completed	
Last Edited 03/10/2017	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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