

Randomized, double-blind, parallel group, repeat dose pharmacokinetic and pharmacodynamic study of four doses of ATL-962 (40 mg, 80 mg, 120 mg 240 mg tid) in otherwise-healthy, obese volunteers

Submission date

06/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

16/09/2005

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

19/02/2020

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Lawrence Galitz

Contact details

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United States of America
FL 33181

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00148382

Protocol serial number

ATL-962/191/CL

Study information

Scientific Title

Randomized, double-blind, parallel group, repeat dose pharmacokinetic and pharmacodynamic study of four doses of ATL-962 (40 mg, 80 mg, 120 mg 240 mg tid) in otherwise-healthy, obese volunteers

Study objectives

What are the pharmacokinetics of the metabolites of ATL-962 and what effect does ATL-962 have on faecal fat excretion in obese subjects

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)

Not Specified

Health condition(s) or problem(s) studied

Obesity

Interventions

ATL-962 40 mg, 80 mg, 120 mg or 240 mg three times a day for 14 days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

ATL-962

Primary outcome(s)

Pharmacokinetics of the metabolites of ATL-962, namely ATL-1143 and ATL1277

Key secondary outcome(s)

Change from baseline in faecal fat excretion.
Safety and tolerability

Completion date

31/07/2005

Eligibility

Key inclusion criteria

Obese, otherwise-healthy, subjects, aged 18-40, with a body mass index between 30 kg/m² and 45 kg/m².

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 years

Upper age limit

40 years

Sex

Not Specified

Key exclusion criteria

1. Women who are pregnant or breast feeding
2. Any drug treatment within 2 weeks of commencement of dosing in this study

Date of first enrolment

01/04/2005

Date of final enrolment

31/07/2005

Locations

Countries of recruitment

United States of America

Study participating centre

SFBC International, Inc

Miami

United States of America

FL 33181

Sponsor information

Organisation

Alizyme (UK)

Funder(s)

Funder type

Industry

Funder Name

Alizyme

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration