

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	<input type="checkbox"/> Prospectively registered
Registration date 16/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/02/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
NCT00148382

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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

Secondary outcome measures

Change from baseline in faecal fat excretion.

Safety and tolerability

Overall study start date

01/04/2005

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

Age group

Not Specified

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Not Specified

Target number of participants

80

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)

Sponsor details

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Sponsor type

Industry

Website

www.alizyme.com

Funder(s)

Funder type

Industry

Funder Name

Alizyme

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