ISRCTN35772094 https://doi.org/10.1186/ISRCTN35772094

# 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

**Registration date**
16/09/2005

**Last Edited**
19/02/2020

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Great Abington
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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