ISRCTN62647464 https://doi.org/10.1186/ISRCTN62647464

Phase II, multicentre, double blind, placebo controlled, parallel group, dose ranging study of ATL-962 (cetilistat) to assess weight loss, safety and tolerability in obese patients with Type II diabetes being treated with metformin, in comparison with orlistat

Submission date
05/09/2005

Recruitment status
No longer recruiting

Registration date
16/09/2005

Overall study status
Completed

Last Edited
14/10/2009

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter Kopelman

Contact details
Barts and The London
Queen Mary's School of Medicine & Dentistry
30-32 Newark Street
London
United Kingdom
E1 2AA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ATL-962/175/CL, orlistat

Study information

Scientific Title

Study objectives
Does ATL-962 induce weight loss in diabetic patients and is its safety and tolerability profile superior to that of orlistat in such patients?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised three arm placebo controlled parallel group 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 in patients with Type II diabetes

Interventions
ATL-962 (40 mg, 80 mg, or 120 mg), or placebo, or orlistat (120 mg) three times a day for 12 weeks

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ATL-962 (cetilistat), orlistat, metformin

Primary outcome measure
Absolute weight loss compared to baseline

Secondary outcome measures
Proportion of patients achieving 5% or 10% weight loss; changes in waist circumference; changes in lipid profiles; changes in markers of diabetes; incidence of GI adverse events; changes in other safety parameters

Overall study start date
01/12/2004

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Type II diabetic patients
2. Aged 18-65
3. Body Mass Index (BMI) between 28 kg/m2 and 45 kg/m2
4. Glycosylated haemaglobin (HbA1c) value between 6% and 10%
5. Being treated with a stable dose of metformin

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Not Specified

Target number of participants
600 patients randomised

Key exclusion criteria
1. Significant weight loss in the previous 3 months
2. Weight gain during the run-in period
3. Other serious systemic disease, except for controlled hypertension, mild asthma, and primary

hypothyroidism
4. History of GI disorders
5. Previous surgery for weight loss

Date of first enrolment
01/12/2004

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and The London
London
United Kingdom
E1 2AA

Sponsor information

Organisation
Alizyme (UK)

Sponsor details
Granta Park
Great Abington
Cambridge
United Kingdom
CB1 6GX
+44 (0)1223 896 000
Medical.Information@alizyme.co.uk

Sponsor type
Industry

Website
http://www.alizyme.com

Funder(s)

Funder type
Industry

Funder Name
Alizyme (UK)

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	01/01/2010		Yes	No