

Orlistat therapy in clozapine- and olanzapine-treated patients who are overweight or obese

Submission date 19/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/05/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/07/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Grigori Joffe

Contact details
Hospital of Kellokoski
Kellokoski
Finland
04500
+358 (0)405 136500
grigori.joffe@hus.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
02T-134

Study information

Scientific Title

Study objectives

Orlistat is better than placebo in olanzapine- or clozapine-treated psychiatric patients who are overweight or obese.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethics Committee for Pediatrics, Adolescent Medicine and Psychiatry, Hospital District of Helsinki and Uusimaa on the 16th June 2002 (ref: 314/E7/02).

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

Obesity

Interventions

Orlistat medication plus education about lifestyle habits

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Orlistat, clozapine, olanzapine

Primary outcome measure

Weight loss

Secondary outcome measures

1. Number of responders (persons with weight loss of 5% or more)
2. BMI
3. Waist measurement
4. Lipids

Overall study start date

01/01/2003

Completion date

31/12/2004

Eligibility

Key inclusion criteria

Male or female in- or out-patients will be recruited if they:

1. Are aged 18 - 65 years
2. Have had a psychotic disorder which is currently under a reasonably good (according to the investigators judgement) control with on-going clozapine or olanzapine therapy i.e. a shift to another antipsychotic or augmentation with another psychotropic drug is not expected during at least the next several months
3. Have had an underlying psychotic disorder, the nature of which, requires prolonged antipsychotic medication i.e. discontinuation of antipsychotic medication is not expected during at least the next several months
4. Have a body mass index (BMI) of 28 - 43 kg/m²
5. The patient has a level of understanding enabling reasonable cooperation with the investigator and likely able to comply with the study protocol, including dietary restrictions
6. Have given written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

Key exclusion criteria

At screening:

1. Previous exposure to orlistat
2. General contraindications to orlistat therapy e.g. chronic malabsorption syndrome or cholestasis
3. Current treatment with weight loss medications
4. Other than clozapine or olanzapine psychotropic or somatic medication known to either

significantly increase or decrease body weight (e.g. some antipsychotics, antidepressants, mood stabilizers etc.) is not allowed. However, if necessary, such a medication can be continued, provided that both the medication and weight have remained stable during four weeks prior to enrolment.

5. Serious physical illness

6. Diabetes mellitus (DM), type I (patients with DM type II are not excluded)

7. History of substance addiction or abuse within less than or equal to 3 months prior to enrolment

8. Expected poor compliance with the study protocol and/or poor control of fat intake

9. For females of child-bearing potential: pregnancy, lactation, or inability or unwillingness to use medically acceptable contraception means during the study

10. Significant (greater than or equal to 1 kg) weight change within less than or equal to 4 weeks prior to enrolment

11. Polydipsia, bulimia, binge-eating, or other condition with rapid unexpected weight changes

At baseline (in addition to those at screening):

1. Clinically relevant abnormalities in the laboratory tests

2. Poor compliance at screening e.g. inaccurate intake of study drug (investigators decision)

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Finland

Study participating centre

Hospital of Kellokoski

Kellokoski

Finland

04500

Sponsor information

Organisation

The Stanley Medical Research Institute (SMRI) (USA)

Sponsor details

5430 Grosvenor Lane

Suite 200

Bethesda

United States of America

MD 20814-2142
+1 301 571 0760 ext. 119
Herrerax@stanleyresearch.org

Sponsor type

Research organisation

Website

<http://www.stanleyresearch.org>

ROR

<https://ror.org/01pj5nn22>

Funder(s)

Funder type

Research organisation

Funder Name

The Stanley Medical Research Institute (SMRI) (USA)

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	01/03/2011		Yes	No