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

Submission date	Recruitment status	[_] Prospectively registered
19/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/07/2011	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
02T-134

Study information

Scientific Title

Study objectives

Orlistat is better then 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

Study type(s)
Treatment

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(s)
Weight loss

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

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/m^2
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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/01pj5nn22

Funder(s)

Funder type
Research organisation

Funder Name
The Stanley Medical Research Institute (SMRI) (USA)

Results and Publications

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