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Efficacy of the BELA weight management programme to prevent increase of weight in schizophrenic patients treated with olanzapin (BELA = movement - nutrition - learning - accepting)

Submission date
18/04/2008

Recruitment status
No longer recruiting

Registration date
30/05/2008

Overall study status
Completed

Last Edited
30/05/2008

Condition category
Mental and Behavioural Disorders

[ ] 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

Secondary identifying numbers
GM2_2007

Study information

Scientific Title

Acronym
BELA

Study objectives
To assess the efficacy of preventative effects of the BELA programme on weight and metabolic parameters in schizophrenic patients treated with olanzapin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Medical Faculty of Heinrich-Heine University. Date of approval: 07/02/2008 (ref: MC-LKP-249)
2. Federal Institute for Drugs and Medical Devices (BfArM). Date of approval: 06/12/2007 (ref: 4033665)

Study design
Phase IV, multi-centre, open, two-arm randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Schizophrenia

Interventions

This trial is taking place at four sites (Düsseldorf, Bochum, Krefeld, Dortmund). Participants will be randomly allocated to the two arms in equal numbers:

Intervention group: Standard therapy + BELA weight management programme
Control group: Standard therapy only

The psychoeducation programme BELA has been developed at the beginning of 2005 for psychiatric patients. The contents of the psychoeducation are based on the knowledge that better nutrition and regular exercise may stabilise the individual course of disease, the detection of bad habits and the implementation, practice and stabilisation of individual, appropriate habits. As far as methods are concerned, these are simple pedagogic and informational modules (adapted to the type of patients) and which result in experiment-orientated, practical exercises. The BELA concept is geared to small groups (6 - 10 patients) in order to, for example, allow the planning, shopping, cooking of a meal. Over a period of 10 weeks there are group meetings, each 60 minutes, with knowledge transfer of nutrition and exercising.

Content of patient-education:
1. Aim of the course
2. Energy and calories
3. Types of provisions
4. Major nutrients
5. Pathology
6. Planning the day
7. Fats
8. Recipes
9. Cooking with vegetables, etc. (practical)
10. Relevance of exercises

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Olanzapin

Primary outcome measure
Weight changes in kg, measured at week 1 and week 10.

Secondary outcome measures
1. Influence of the intervention on further risk factors, assessed by the following:
1.2. Cholesterol at Week 2, 1, 5, 10, 14 and 18
1.3. low density lipoprotein (LDL) at Week 2, 1, 5, 10, 14 and 18
1.4. Triglyzeride at Week 2, 1, 5, 10, 14 and 18
1.5. high density lipoprotein(HDL) at Week 2, 1, 5, 10, 14 and 18
1.6. HbA1c at Week 1, 10 and 18
1.7. Glucose at Week 2, 1, 5, 10, 14 and 18
1.8. Blood-pressure at Week 2, 1, 5, 10, 14 and 18
1.9. Abdominal girth at Week 2, 1, 5, 10, 14 and 18
1.10. Body mass index (BMI) at Week 2, 1, 5, 10, 14 and 18

2. Identification of indicators with regard to weight increase and the response on weight management by acquisition of the following parameters:
2.1. Age, sex, initial weight 2 weeks prior to intervention
2.2. Psycho-pathological rating-scales:
a. Positive and Negative Syndrome Scale (PANSS) 2 weeks before intervention and then at weeks 1, 5, 10, 14 and 18
b. Personal social achievement rating scale (persönliche soziale Leistungskala [PSL]) at weeks 1, 10 and 18
c. 36-item Short Form health survey (SF-36) at weeks 1, 10 and 18
d. Body image assessment questionnaire (Fragebogen zur Beurteilung des eigenen Körpers [FBeK]) at weeks 1, 10 and 18
e. Type D Personality Scale (DS14) 2 weeks prior to intervention
f. Global Assessment of Functioning (GAF) at weeks 1, 10 and 18
2.3. Medical genetics: Polymorphism for weight increase, assessed at week 1
2.4. Lipometabolism: Participating hormones and interleukine: leptin, ghrelin, adiponektin, cortisone, retinol binding protein 4 (RBP-4), IL-6, TNF-alpha. These will be assessed at weeks 1, 10 and 18
3. Increase of weight (in kg) of the intervention group in comparison to the control group at the end of the follow-up phase (Week 1 [before the intervention phase] vs Week 18 [after the follow-up phase])

Overall study start date
03/04/2008

Completion date
15/11/2010

Eligibility

Key inclusion criteria
1. Both males and females
2. Age 18 - 65 years
3. Criteria of the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM IV) for schizophrenia or schizoaffective psychosis
4. Written informed consent
5. Capability of signing informed consent
6. Olanzapin medication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

180

Key exclusion criteria
1. Serious somatic diseases
2. Changes in weight due to somatic diseases
3. Pregnancy or lactation
4. Increase of weight of more than 3 kg over the last 3 months before start of treatment with olanzapin
5. Co-medication with a weight-reducing potential
6. Participation in another interventional trial which could interfere with this trial

Date of first enrolment
03/04/2008

Date of final enrolment
15/11/2010

Locations

Countries of recruitment
Germany

Study participating centre
Clinic and Polyclinic for Psychiatry and Psychotherapy
Düsseldorf
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40629

Sponsor information

Organisation
Heinrich-Heine University (Germany)

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Sponsor type
University/education

Website
http://www.uni-duesseldorf.de

ROR
https://ror.org/024z2rq82

Funder(s)

Funder type
University/education

Funder Name
Heinrich-Heine University (Germany)

Funder Name
Lilly GmbH (Germany)

Funder Name
Note: This is an investigator initiated trial.

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