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Examining the effectiveness of oxytocin in improving treatment for anorexia nervosa

Submission date
22/06/2015

Recruitment status
Stopped

Registration date
06/08/2015

Overall study status
Stopped

Last Edited
18/11/2015

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

Background and study aims
Anorexia nervosa (AN) is a major social and public health problem with the highest death rate and treatment costs of any psychiatric disorder. Effective nutritional rehabilitation programs exist but are costly and protracted, and patients struggle to engage and persevere. There is an urgent need for a safe, inexpensive, easily administered treatment to help nutritional rehabilitation programs work better and encourage patients to comply with them. The purpose of this study is to investigate a novel pharmacotherapy, intra-nasal oxytocin (IN-OT) and its effects on patients with anorexia nervosa participating in a nutritional rehabilitation program. Oxytocin (OT) has shown promise in treating some forms of mental illness through its prosocial and anxiolytic (anxiety lowering) effects.

Who can participate?
Adult women diagnosed with AN and fluent in English, recruited in Sydney (Austria) and London (UK).

What does the study involve?
All inpatients at both clinics are given the study information sheet and provided with an opportunity to ask any questions they might have about the study. If a patient decides to take part in the trial they are provided with further information, screened for eligibility and asked to sign a consent form. The participant is then randomised into either the oxytocin (intervention) or placebo (control) group. Each participant is asked to participant in an initial assessment at the start of the study to assess how severe their eating disorder is, and their neuropsychological (brain) functioning. They are then asked to take part in two embedded single dose studies at the beginning and at the end of the trial. The single dose studies involve each participant giving themselves 18 IU of oxytocin or placebo before eating a afternoon snack and completing a questionnaire measuring anxiety. This same procedure is repeated at the end of the trial (57th dose). After the first embedded single dose study the main trial begins, during which participants are asked to self-administer intra-nasal oxytocin (18 IU) or placebo twice a day (at 10am and 3pm) under the supervision of a medically trained member of the research team. Participants are monitored throughout the trial for adverse reactions by a medically trained

member of the research team as well as by clinic staff. After the trial has finished participants are followed up at regular intervals (1, 6 and 12 months) to assess outcome and service use (e.g. eating disorder related visits to the GP).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Bethlem Royal Hospital (London) and Biden Institute (Australia)

When is the study starting and how long is it expected to run for?
May 2015 to July 2017

Who is funding the study?
National Health and Medical Research Council (Australia)

Who is the main contact?
Professor Janet Treasure
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial to examine the effectiveness of oxytocin to improve treatment for anorexia nervosa

Study objectives
Primary Aim. To assess the efficacy of repeated dosing with intra-nasal oxytocin (IN-OT) versus placebo in treating core eating disorder psychopathology and in improving response to nutritional rehabilitation across 28 days of inpatient treatment.

Hypothesis 1: Patients treated with daily IN¬OT (36 IU per day) will show greater improvements in core eating disorder psychopathology and disordered eating behaviours with greater gains in BMI across inpatient treatment.

Secondary Aims: To assess the efficacy of the first and final daily dose of IN-OT in reducing food related anxiety in response to a high -energy snack.
Hypothesis 2: Oxytocin (OT) treated patients will display lower levels of pre snack anxiety, show reduced levels of salivary cortisol and alpha--amylase in anticipation of a high energy snack compared to patients who received placebo after the initial dose and after repeated dosing with IN-OT.

Aim 3: To assess the effects of repeated dosing with IN-OT on motivation and cognition during inpatient nutritional rehabilitation treatment for AN.
Hypothesis 3: Patients receiving repeated treatment with IN-OT will display improved motivation to change and reduced cognitive rigidity relative to placebo after 28 days of inpatient treatment.

Aim 4: To assess the long-term impact of chronic (4 weeks) IN-OT treatment on 1, 6 and 12 month outcomes.
Hypothesis 4: IN-OT- treated patients will show continued gains, less service utilisation (days in hospital, medical and emergency presentations) and improved functional outcomes at 1, 6 and 12 months compared to those in the placebo group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A randomized double blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Anorexia nervosa.

Interventions
This project will use a randomized double blind placebo-controlled design to compare the effects of repeated twice daily-dosing of intra-nasal oxytocin as an adjunct to inpatient nutritional rehabilitation treatment. Both oxytocin and placebo arms will receive standard inpatient treatment. The average minimum inpatient treatment stay of 4 weeks (28 days) will be used as the intervention period to ensure compliance with dosing and to minimise drop-outs. Participants will 36 IU of oxytocin delivered in two daily (18IU each) doses intra-nasally for the entire 4 weeks. Embedded within the overall design, will be a Single Dose Study whereby the effects of the first and final dose (57th dose) of oxytocin on anxiety and stress related to feeding, and disordered eating behaviour, will be specifically evaluated.

Intervention Type
Biological/Vaccine

Primary outcome measure
Core eating disorder psychopathology and BMI will be measured using the Eating Disorder Examination semi-structured interview and height and weight measurements at pre (week 0) and post (week 4) intervention, as well as at 1, 6 and 12 months follow-up.

Secondary outcome measures
1. Motivation to change assessed using the Anorexia Nervosa Stages of Change Questionnaire (ANSOCQ) at pre (week 0) and post (week 4) intervention
2. Cognitive rigidity will be assessed using the Cognitive Flexibility Scale (CFS) and the Wisconsin Card
3. Sorting Test (WCST) at pre (week 0) and post (week 4) intervention
4. Service utilisation will be assessed in a follow-up interview at 1, 6 and 12 months follow-up
5. Functional outcomes will be assessed using the Morgan-Russell Average Outcome Scale (MRAOS) at 1, 6 and 12 months follow-up
6. Pre and post snack VAS anxiety scores, and salivary cortisol, alpha-amylase and OT will be assessed in the two embedded single-dose studies on day 1 (week 0) and day 28 (week 4)

Overall study start date
01/05/2015

Completion date
01/07/2017

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Female and fluent in English
2. Diagnosis of eating disorders (anorexia nervosa)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
30

Key exclusion criteria
1. Non-proficiency in the English language (as needed for neuropsychological tests)
2. IQ <80 (National Adult Reading Test; NART)
3. Currently pregnant
4. Current manic episode or psychosis
5. Current alcohol, substance abuse or dependence
6. Acute suicidality
7. Significant medical or neurological disorders not relating to their primary diagnosis of AN
8. Conditions such as major septal deviation or other nasal conditions
9. Patients being treated under the Mental Health Act or under compulsory treatment orders
10. Patients previously given OT or those with planned stays in hospital of less than 4 weeks
11. Patients with an ECG of less than 40 beats per minute to avoid the potential hypotensive effects of OT

Date of first enrolment
01/07/2015

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
Australia

England

United Kingdom

Study participating centre

Bethlem Royal Hospital
Monks Orchard Road
Beckenham
London
United Kingdom
BR3 3BX

Study participating centre
Biden Institute
Charles Perkins Centre
University of Sydney
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NSW 2006

Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Health and Medical Research Council

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan
It is intended that the results of the study will be reported and disseminated at international conferences and in peer-reviewed scientific journals. No dates as of yet.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request