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'Eat Smart for Success': Investigating the use of pharmacotherapy in adolescents for weight loss maintenance: The role of appetite

Submission date	Recruitment status	[ ] Prospectively registered
07/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/11/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/05/2013	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www2.som.uq.edu.au/som/Research/ResearchCentres/cnrc/Pages/CNRCHome.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Investigating the use of pharmacotherapy in adolescents for weight loss maintenance: The role of appetite: A randomised, placebo controlled trial

Study objectives
1. Metformin will prevent weight regain in obese adolescents after a period of weight loss
2. Metformin improves satiety such that the drive to eat and food intake are reduced
3. Metformin causes a decrease in circulating orexogenic hormones (Ghrelin) and an increase in anorexigenic hormones (Glucagon-Like Peptide 1 [GLP-1], pancreatic polypeptide [PP] and peptide YY [PYY]) both acutely and after chronic administration
4. Food preferences and the drive to eat differ between obese adolescents and their healthy weight peers

Please note that as of 15/05/2013, the anticipated end date for this trial was updated from 30/06/2013 to 30/06/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Human Research Ethics Committee (HREC) of the Royal Children's Hospital (ref: HREC/10/QRCH/53)

Study design
Single centre randomised placebo controlled parallel group 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 information below to request a patient information sheet

Health condition(s) or problem(s) studied

Adolescent Obesity

Interventions
Obese adolescents (12-18 years with BMI z-score >95th Centile for age) will be randomised to receive metformin or placebo orally.
Starting dose will be 500mg (1 tablet) bd, increasing to 500mg (1 tablet) every morning/mane and 1g (2 tablets) every evening/nocte at 2 weeks, increasing again to 1g (2 tablets) bd at 1 month for the remainder of the trial
The total length of the intervention will be 6 months.
Medication is to be taken with meals and doses where participants come to the hospital for testing, will be supervised. Complicance overall will be monitored by the study pharmacist by pill counting.

All subjects will receive lifestyle intervention - structured dietary restriction and general advice on increasing physical activity

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome measure
BMI (pre and post intervention)

Secondary outcome measures
1. Subjective appetite sensations using a novel Electronic appetite Rating system (EARS), immediately before and then hourly for 4 hours after a fixed-energy breakfast. Measured at baseline, day 1, week 2, week 4, then monthly. This is a validated technique of measuring appetite which has been used in appetite studies involving obese children.
2. Food preferences will be measured using a novel 'liking and wanting' (L&W) experimental procedure. Measured at baseline, day 1, week 2, week 4, then monthly. This method has been validated in several studies. The L&W procedure is sensitive to detect changes in nutrient and taste preferences.
3. We will measure fasting gastrointestinal hormones (at baseline, day 28, 2mo and 6mo) to identify potential biomarkers which could explain any differences in appetite responses between the two groups. These will be correlated with fasting and postprandial subjective appetite sensations.
4. In a subset of patients (10 in each group), we will measure the gastrointestinal hormones and subjective sensations of appetite, pre- and postprandially (by insertion of an intravenous cannula) and pre and post dosing with metformin. These measurements will be taken at baseline, each metformin dose increment (d1, wk2, wk4), 2mo and 6mo.

Overall study start date
01/07/2010

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. 12-18 years
2. BMI >95th centile for age and gender
3. Pubertal stage ≥3
4. Ability for parent and child to read and understand written instructions in English; parents able to give informed written consent in English; adolescent able to give verbal assent
5. Successfully completed a 6 month lifestyle intervention without a gain in BMI z-score

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Those with renal disorders, diabetes, diagnosed psychological disorders
2. Those taking stimulants or psychotropic medication or drugs known to alter metabolism including insulin sensitisers, glucocorticoids, thyroxine, other weight loss medications
3. Those taking any drugs known to be contraindicated with metformin therapy
4. Known adverse reactions to metformin
5. Pregnancy

Date of first enrolment
01/07/2010

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Australia

Study participating centre

Department of Endocrinology and Diabetes
Herston, Qld
Australia
4029

Sponsor information

Organisation
Royal Children's Hospital (Australia)

Sponsor details
Herston Road
Herston, Queensland
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02rktxt32

Funder(s)

Funder type
Industry

Funder Name
Australian Paediatric Endocrine Care (APEC) Research Grant (Pfizer) (Australia) - (ref: E/09) (contact: trudy.snape@pfizer.com)

Funder Name
Royal Children's Hospital (Australia)

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