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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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
BMI (pre and post intervention)

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit

12 years

### Upper age limit
18 years

### Sex
All

### 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)

### 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

### 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? |
|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |