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# Metformin in Obese Children with Abnormal Glucose and Insulin Status

**Submission date**
29/09/2006

**Recruitment status**
No longer recruiting

**Registration date**
29/09/2006

**Overall study status**
Completed

**Last Edited**
07/01/2013

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims:
Childhood obesity has increased globally over the last two decades and it is linked to an increase in the diagnosis of type 2 diabetes (T2D) in childhood and adolescence. T2D is a condition that was previously only diagnosed in adults and was very rare in children. T2D is associated with high blood glucose levels and with other significant health problems, such as increased risk of heart problems, eye problems, kidney problems, nerve problems and premature death. It is therefore important to try to prevent the onset of T2D in obese children and adolescents.
Metformin is a drug that reduces the risk for T2D in obese adults, but the evidence in obese children and young people is inconclusive. The aims of the MOCA trial were to find out how well metformin works in obese children and adolescents.

Who can participate?
One hundred and fifty-one obese children and young people took part in the trial with 74 in the metformin group and 77 in the dummy (placebo) group. 67.5% were female, and 23.8% were British Asian or Afro-Caribbean. The age range was 8-18 years, with an average age of 13.7 years.

What does the study involve?
The MOCA trial was a prospective clinical trial over six months, where the participants were put into two groups randomly by chance. One group was given treatment with metformin and one group was given a dummy pill (placebo). Neither the participant or study investigator knew whether the participant was taking the metformin or placebo. All the participants were obese and they visited the trial centre at the start of the trial, after 3 months treatment and after 6 months treatment (the end). At each visit they had blood tests done and their weight and height was measured so that their body mass index (BMI) could be calculated (weight in kg/height in m2). The BMI was then adjusted for age and sex to give the body mass index standard deviation score (BMI-SDS).

What are the possible benefits and risks of participating?
Benefits of participating include a potential reduction in long-term risk of T2D and associated health problems. The risks associated with participating were small as metformin is safe and well tolerated with minimal side-effects in obese children and adolescents.

Where is the study run from?
The trial took place in six UK paediatric endocrine centres.

When is the study starting and how long is it expected to run for?
The study began in January 2005 and ended in June 2009.

Who is funding the study?
Central Manchester University Hospitals NHS Foundation Trust and the Child Growth Foundation UK.

Who is the main contact?
Peter E Clayton MD MRCP FRCPCH
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Peter Clayton

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# Additional identifiers

### Protocol serial number
N0453162755

# Study information

### Scientific Title

### Acronym
MOCA

### Study objectives
To study the effects of metformin in children and adolescents with fasting hyperinsuliaemia and /or impaired glucose tolerance.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Added 16 December 2008: Salford and Trafford Research Ethics Committee, 13/09/2004, REC reference no: 04/Q1404/65.

### Study design
Multicentre prospective randomised placebo controlled

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Obesity

### Interventions
Previous interventions:
1. Metformin (500mg)
2. Placebo

Current interventions as of 15/12/2008:
1. Metformin 1g mane, 500mg nocte
2. Placebo

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
metformin

### Primary outcome(s)
Reduction in BMI SDS.

### Key secondary outcome(s))
Added 16 December 2008: fasting and 2 hr insulin and glucose levels on OGTT, measures of insulin resistance, fasting lipids, CRP, adiponectin, leptin, resistin, blood pressure.

### Completion date
30/06/2009

## Eligibility

### Key inclusion criteria
Prior to 16 December 2008:
80 patients aged between 9-18 years old

As of 16 December 2008:
1. Pubertal and post-pubertal children : Fasting insulin > 26 mIU/l
2. Pre-pubertal children : Fasting insulin > 15 mIU/l
3. 120 minute insulin > 89 mIu/l
AND/OR
Impaired glucose tolerance ie: OGTT 2hr plasma glucose value > or = 7.8 to <11.1 (+/- impaired fasting glucose > or = 6.1 to < 7)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
9 years

### Upper age limit
18 years

### Sex
Not Specified

### Key exclusion criteria
Added 16 December 2008:

1. Glycosuria
2. Ketonuria
3. Other chronic illness or chromosomal abnormality or syndrome eg. Prader-Willi, Turners syndrome, hypothyroidism
4. Renal insufficiency
5. Hepatic dysfunction (raised ALT >2 SDS above mean)
6. Chronic diarrhoea
7. Previous episode lactic acidosis

### Date of first enrolment
01/01/2005

### Date of final enrolment
30/06/2009

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Manchester Academic Health Sciences Centre**
Manchester
United Kingdom
M13 9WL

## Sponsor information

### Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

## Funder(s)

### Funder type
Charity

### Funder Name
Central Manchester and Manchester Children's University Hospitals NHS Trust (UK) - NHS R&D Support Funding

### Funder Name
Child Growth Foundation

## 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 | 01/01/2013 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |