

Metformin in Obese Children with Abnormal Glucose and Insulin Status

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/01/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0453162755

Study information

Scientific Title

Acronym

MOCA

Study objectives

To study the effects of metformin in children and adolescents with fasting hyperinsulinaemia 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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

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

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 measure

Reduction in BMI SDS.

Secondary outcome measures

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.

Overall study start date

01/01/2005

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

Age group

Child

Lower age limit

9 Years

Upper age limit

18 Years

Sex

Not Specified

Target number of participants

40 in each group, 80 in total.

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

England

United Kingdom

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

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Sponsor type

Government

Website

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2013		Yes	No