

# Insulin resistance and obesity in adolescents - metabolic characterisation and effects of therapeutic intervention with metformin

**Submission date**  
16/11/2004

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
13/01/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
12/01/2021

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Geoff Ambler

### Contact details

Institute of Endocrinology and Diabetes  
The Children's Hospital at Westmead  
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Westmead NSW  
Australia  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Insulin resistance and obesity in adolescents - metabolic characterisation and effects of therapeutic intervention with metformin

### Study objectives

Not provided at time of registration

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Insulin resistance and obesity

### Interventions

Metformin vs placebo (crossover design)

### Intervention Type

Drug

### Phase

Not Specified

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

Metformin

### Primary outcome measure

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2005

**Completion date**

31/12/2005

## **Eligibility**

**Key inclusion criteria**

Children and adolescents age 9-18 with obesity and insulin resistance, pre-type 2 diabetes.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Total final enrolment**

28

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2005

**Date of final enrolment**

31/12/2005

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

Institute of Endocrinology and Diabetes

Westmead NSW

Australia  
2145

## Sponsor information

### Organisation

The Children's Hospital, Westmead - Research and Development Office (Australia)

### Sponsor details

Locked Bag 4001  
Westmead NSW  
Australia  
2145

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/05k0s5494>

## Funder(s)

### Funder type

Charity

### Funder Name

Diabetes Australia Research Trust

## 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?
<a href="#">Results article</a>	results	01/06/2006	12/01/2021	Yes	No