

# Early Diabetes Intervention Trial

<b>Submission date</b> 19/06/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/06/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/01/2011	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.dtu.ox.ac.uk/edit/protocol.php>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Rury R Holman

### Contact details

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United Kingdom  
OX3 7LJ

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

Study Numbers: Bay g 5421/0740 and Bay g 5421/200031

# Study information

## Scientific Title

## Acronym

EDIT Study

## Study objectives

The Early Diabetes Intervention Trial (EDIT) was a six-year, prospective, randomised, double-blind, placebo-controlled study in subjects thought to be at increased risk of developing diabetes, and who had two consecutive fasting plasma glucose levels in the range 5.5 to 7.7 mmol/L. The primary aim of the trial was to determine whether deterioration in glycaemic tolerance towards diabetes could be delayed or prevented using an alpha-glucosidase inhibitor (acarbose) or a biguanide (metformin). The trial results were presented at the 2003 Diabetes UK meeting.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Prospective, randomised, double-blind, placebo-controlled study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Not Specified

## Participant information sheet

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

Impaired glucose tolerance

## Interventions

Subjects valid for inclusion were randomly assigned to acarbose 50 mg tds, metformin 500 mg tds, a combination of the two, or matching placebo.

## Intervention Type

Drug

**Phase**

Not Specified

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

acarbose, metformin

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1997

**Completion date**

31/12/2003

## Eligibility

**Key inclusion criteria**

Subjects aged 30 to 70 years inclusive, with fasting hyperglycaemia; defined as a fasting plasma glucose (FPG) level  $\geq 5.5$  mmol/l and  $< 7.8$  mmol/l on two occasions at least 1 week apart

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

631

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/1997

**Date of final enrolment**

31/12/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Diabetes Trials Unit**

Oxford

United Kingdom

OX3 7LJ

## **Sponsor information**

**Organisation**

Bayer plc and Merck-Lipha (UK)

**Sponsor details**

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United Kingdom

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**Sponsor type**

Industry

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Educational grants were provided by Bayer plc and Merck-Lipha (UK)

## **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="#">Abstract results</a>				No	No
<a href="#">Abstract results</a>				No	No
<a href="#">Abstract results</a>	abstract 450-P	01/06/2000		No	No
<a href="#">Results article</a>	results	01/06/2003		Yes	No
<a href="#">Results article</a>	Hyper Glycaemia results	01/01/2009		Yes	No