ISRCTN96631607 https://doi.org/10.1186/ISRCTN96631607

Early Diabetes Intervention Trial

Submission date
19/06/2002

Recruitment status
No longer recruiting

Registration date
19/06/2002

Overall study status
Completed

Last Edited
06/01/2011

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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 ≥5.5 mmol/l and <7.8 mmol/l on two occasions at least 1 week apart

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Diabetes Trials Unit
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Bayer plc and Merck-Lipha (UK)

Funder(s)

Funder type
Industry

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

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	01/06/2003		Yes	No
Results article	Hyper Glycaemia results	01/01/2009		Yes	No
Abstract results				No	No
Abstract results				No	No
Abstract results	abstract 450-P	01/06/2000		No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes