ISRCTN75451837 https://doi.org/10.1186/ISRCTN75451837

UK Prospective Diabetes Study - post study monitoring (PSM) and cohort follow-up (CFU)

Submission date	Recruitment status
17/10/2000	No longer recruiting
Registration date	**Overall study status**
17/10/2000	Completed
Last Edited	**Condition category**
22/05/2024	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

Study website
http://www.dtu.ox.ac.uk/ukpds

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G8109618 (now incorporates G8815630)

Study information

Scientific Title
-

Acronym
UKPDS

Study objectives
Please note that as of 15/08/2008 this record has been extensively updated and now includes a follow-up study. All details pertaining to these updates can be found in the relevant field under the above update date. At this time, the title of this trial was changed to the above; the previous title was: UK prospective diabetes study - post-study monitoring (PSM). Please also note that the anticipated end date of this trial was extended to 31/12/2007; the previous anticipated end date was 30/09/2002.

Current hypothesis as of 15/08/2008:
To determine whether improved blood glucose control will prevent the complications of type 2 diabetes, and whether any mode of therapy, diet, insulin, sulphonylurea or metformin, has specific advantages or disadvantages. The trial showed that improved blood glucose and blood pressure control did lead to a reduction in the incidence of complications of type 2 diabetes. All contactable surviving patients from the trial are being followed up during the post-study monitoring and the cohort follow-up phases, to track any changes in the incidence of complications. There is no further intervention in these phases. Physicians are responsible for each patient's care. The PSM and CFU phases of the study are examining possible legacy effects10 years post-trial of earlier randomised allocation to more intensive blood glucose and /or blood pressure control.

Previous hypothesis:
To determine whether improved blood glucose control will prevent the complications of type 2 diabetes, and whether any mode of therapy, diet, insulin, sulphonylurea or metformin, has specific advantages or disadvantages. The trial showed that improved blood glucose and blood pressure control did lead to a reduction in the incidence of complications of type two diabetes. All contactable surviving patients from the trial are being followed up during the post-study monitoring phase, to track any changes in the incidence of complications. There is no further intervention in this phase. Physicians responsible for each patient's care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the South East Multi-centre Research Ethics Committee on the 20th September 2002 (MREC 02/01/85)

Study design
Randomized controlled trial

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
Diabetes

Interventions
Diet/insulin/sulphonylurea/metformin in preventing the complications of type 2 diabetes.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Insulin/sulphonylurea/metformin

Primary outcome measure
1. Diabetes-related mortality: deaths from heart attacks, sudden death, stroke, complications from peripheral vascular disease or amputations, renal failure, hyperglycaemic or hypoglycaemic coma.
2. Total mortality
3. Diabetes-related mortality and major clinical endpoints, including non-fatal myocardial infarct, clinical angina with confirmatory abnormal ECG, heart failure, major stroke, retinal photocoagulation, vitreous haemorrhage, blindness, renal failure

Secondary outcome measures
Added 15/08/2008:
1. Quality of life
2. Health economic outcomes
3. Cognitive function

Overall study start date
01/03/1998

Completion date
30/09/2002

Eligibility

Key inclusion criteria

1. Newly diagnosed type 2 diabetic patients
2. Aged 25 - 65 years inclusive (median age 52 years)
3. Two fasting plasma glucose concentrations more than 6 mmol/l

Participant type(s)
Patient

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
5102

Key exclusion criteria
1. Severe vascular disease
2. Accelerated hypertension
3. Proliferative or pre-proliferative retinopathy
4. Renal failure
5. Other life threatening diseases an illness requiring systematic steroids
6. An occupation that precluded insulin therapy
7. Language difficulties
8. Ketouric greater than 3 millimols per litre suggestive of insulin dependent diabetes

Date of first enrolment
01/03/1998

Date of final enrolment
30/09/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Diabetes Trials Unit
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
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Organisation
University of Oxford Diabetes Trials Unit

Sponsor details
Sponsor for the cohort follow-up
OCDEM
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Sponsor type
University/education

Funder(s)

Funder type
Industry

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Several pharmaceutical companies

Funder Name
Other organisations

Funder Name
For a full list of sources of funding for this trial, please visit the trial website at http://www.dtu.ox.ac.uk/ukpds/funding.php

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	UKPDS results:	12/09/1998		Yes	No
Results article	UKPDS results:	12/09/1998		Yes	No
Results article	UKPDS results:	12/09/1998		Yes	No
Results article	UKPDS results:	12/09/1998		Yes	No
Results article	results of 10-year follow-up of intensive glucose control:	09/10/2008		Yes	No
Results article	results of long-term follow-up after tight control of blood pressure:	09/10/2008		Yes	No
Results article	results	05/03/2013		Yes	No
Results article	UKPDS results	01/03/2020	10/02/2020	Yes	No
Results article	UKPDS 89 results	01/08/2021	04/10/2021	Yes	No
Results article	UKPDS 91 results	17/05/2024	22/05/2024	Yes	No