

Modification of carbohydrate quantity and quality whilst increasing mono-unsaturated fatty acid (MUFA) intake in Type 2 Diabetes

Submission date 30/09/2004	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/03/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0203132077

Study information

Scientific Title

Study objectives

Is a low glycaemic load, high mono-unsaturated fat diet superior to the conventional dietary approach in helping factors in Type 2 Diabetes?

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

Nutritional, Metabolic, Endocrine: Diabetes

Interventions

As of 26/03/2013 the status of this record was changed to 'stopped'. The trial was not started due to staff changes.

30-40 patients will be recruited to the study from the Exeter Diabetes and Vascular Health Centre. They will be randomised to receive either low carbohydrate, high MUFA dietary advice or standard low fat dietary advice. Final randomisation numbers are determined by change and concealed from the study worker to ensure that randomisation cannot be predicted as recruitment nears completion. Each group will have group education sessions on a monthly basis, and each individual will receive a one-to-one teaching session with a specialist dietitian. Dietary advice will be constant except for the variables being tested. Thus both groups will be advised to increase fruit and vegetable intake, eat oily fish, and will be instructed to follow a prescribed energy deficit of 750 kcal per day. Each participant will be in the study for 3 months. Patients will carry out food diaries to test to see if they have changed their dietary habits (at end of study), and metabolic parameters (lipids, HbA1c, weight change, blood pressure) will be

measured at baseline and completion. The Diabetes Health Profile 19 will be used as a disease specific quality of life.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Does dietary advice based on the following points help people with Type 2 diabetes?
Lowering the dietary glycaemic load (by restricting carbohydrate intake by quantity and type)
Increasing mono-unsaturate fat intake (nuts/olive oil)
Study endpoints: Change in HbA1c, lipids, body mass, blood pressure, diet achieved, disease specific quality of life, dietary glycaemic load

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2003

Completion date

31/12/2006

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility**Key inclusion criteria**

Type 2 diabetes, Body Mass Index (BMI) >25, HbA1c 6.5% to 12%, ready to change lifestyle.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

40

Key exclusion criteria

Unexplained weight loss or ketosis at baseline assessment, type 1 diabetes. They will be asked by specialist nurses in diabetes or clinicians working with them.

Date of first enrolment

01/10/2003

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Devon & Exeter Hospital (Wonford)

Exeter

United Kingdom

EX2 5DW

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Charity

Funder Name

Royal Devon and Exeter NHS Trust (UK)

Funder Name

Diabetes UK (UK)

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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