

A pilot study to investigate the effects of increasing meal frequency and snacking on blood glucose measurements in patients with type 2 diabetes on insulin treatment

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/05/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0016132016

Study information

Scientific Title

A pilot study to investigate the effects of increasing meal frequency and snacking on blood glucose measurements in patients with type 2 diabetes on insulin treatment

Study objectives

What this study hopes to answer is whether giving appropriate advice on snacking and spreading out the Kcal intake throughout the day reduces the incidence of hypoglycaemia and improves control in patients with type II diabetes on insulin without increasing Kcal intake

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes

Interventions

Inclusion of snacks and reduction of main meal portions will reduce overall measurements of blood glucose and reduce incidence of hypoglycaemic episodes whilst maintaining similar energy intake per day.

The study design is a randomized controlled trial. Subjects will be randomly assigned to intervention or control groups.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The results will be incorporated into the departments dietetic protocol and may be used alter the focus of dietary advice for this patient group to help in the prevention of hypoglycaemia and weight gain. It will also highlight areas for further research.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2003

Completion date

01/05/2004

Eligibility

Key inclusion criteria

Patients with type II diabetes who attend the diabetes clinic chx

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/11/2003

Date of final enrolment

01/05/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Nutrition & Dietetics Department
London
United Kingdom
W12 0HS

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
Hospital/treatment centre

Funder Name
Hammersmith Hospital NHS Trust (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