

Influence of hyperglycaemia on mononuclear cell DNA integrity and gene expression in relation to cardiovascular disease risk

Submission date
30/09/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/09/2004

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
26/04/2018

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ 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

N0547130898

Study information

Scientific Title

Influence of hyperglycaemia on mononuclear cell DNA integrity and gene expression in relation to cardiovascular disease risk

Study objectives

The expression of cardiovascular disease (CVD)-risk-associated genes will be increased at baseline in patients with Type 2 diabetes compared with non-diabetic individuals, and the expression of these genes will be up-regulated following an acute glucose load, and will be repressed following antioxidant supplementation in patients with 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)

Not Specified

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Diabetes

Interventions

Not provided at time of registration

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Controls will be recruited from the Institute of Food Research's (IFR's) Human Nutrition Unit volunteer database, the Diabetes Centre database and by media reporting (local newspaper feature).

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2003

Completion date

01/10/2005

Eligibility

Key inclusion criteria

30 patients with type 2 diabetes and 30 controls

Participant type(s)

Mixed

Age group

Not Specified

Sex

Not Specified

Target number of participants

60

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2003

Date of final enrolment

01/10/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital NHS Trust
Norwich
United Kingdom
NR4 7UY

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
Government

Funder Name
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital
/Norwich PCT (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