ISRCTN20662850 https://doi.org/10.1186/ISRCTN20662850

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

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/04/2018	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Mike Sampson

Contact details
Consultant Physician
Department of Diabetes and Endocrinology
Level 3, East Wing
Norfolk and Norwich University Hospital NHS Trust
Norwich
United Kingdom
NR4 7UY
+44 (0)1603 287094
mike.sampson@nnuh.nhs.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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).

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

Completion date
01/10/2005

Eligibility

Key inclusion criteria
30 patients with type 2 diabetes and 30 controls

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital /Norwich PCT (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes