ISRCTN46349186 https://doi.org/10.1186/ISRCTN46349186

Improving glycaemic control with L carnitine

Submission date	Recruitment status	[X] Prospectively registered
25/07/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/07/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2020	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 Francis Stephens

Contact details
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH
+44 115 823 0398
francis.stephens@nottingham.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02197299

Protocol serial number
16883

Study information

Scientific Title
Increasing skeletal muscle carnitine content to improve glycaemic control in type 2 diabetes mellitus

Study objectives
A characteristic of Type 2 diabetes is a high blood glucose level, which is partly caused by the inability of insulin to stimulate glucose uptake into our muscles (insulin resistance). Insulin resistance can be caused by the accumulation of fat within muscle of overweight individuals. The aim of the present research is to test whether a novel nutritional intervention containing L-carnitine can increase the amount of carnitine within muscle of individuals recently diagnosed with Type 2 diabetes. Carnitine is essential for 'burning fat' within our muscles and it is hoped that increasing the amount of carnitine within muscle can increase fat burning, lower muscle fat, reverse insulin resistance and ultimately lower blood glucose levels and wellbeing. We also aim to investigate the cellular mechanisms underlying any observed effects in a hope to identify further targets to lower muscle fat.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/04/2014, ref: 14/EM/0136

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Carnitine, Oral administration of 4.5 g L-carnitine L-tartrate (containing 3 g L-arnitine; Carnipure, Lonza Ltd., Switzerland) once daily for 24 weeks

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
Skeletal muscle total carnitine content is measured at baseline and 24 weeks.

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

Completion date
31/07/2016

Eligibility

Key inclusion criteria
Inclusion criteria patients with T2DM:
1. Body mass index (BMI) 27--37 kg/m2
2. Male
3. Age 18--60 years old
4. Type 2 diabetes mellitus reasonably well controlled (HbA1c less than or equal to 58 mmol /mol) on diet therapy or metformin alone
5. Not taking anti--diabetes medication other than metformin
6. Understand verbal and/or written explanation of the study requirements

Inclusion criteria control participants:
1. Body mass index (BMI) 27--37 kg/m2
2. Male
3. Age 18--60 years old
4. Normal glucose tolerance (2 hour blood glucose <5.6 after screening OGTT)
5. Not taking anti--diabetes medication
6. Understand verbal and/or written explanation of the study requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Male

Key exclusion criteria
1. Malignancy (excluding localised basal and squamous cell skin cancer)
2. Metabolic diseases (stable treated hypothyroidism allowed)
3. Active cardiovascular disease (current angina, myocardial infarct, or coronary artery surgery /angioplasty within 12 months)
4. Primary muscle disorders
5. Cerebrovascular disease
6. Neurological disease e.g. epilepsy, Parkinsons disease
7. Active respiratory disease
8. Active gastrointestinal or liver disease
9. Renal impairment (eGFR <60 ml/min)
10. Clotting dysfunction
11. Anti--diabetes medication other than metformin
12. Other medications that may affect glucose tolerance (e.

g. corticosteroids), muscle metabolism, or safety (e.g. anticoagulants)
13. Any other conditions in addition to the above that the investigators consider may affect study r

14. Abnormalities on screening blood tests that in the view of the investigators are clinically signifi

15. Any metallic implants that will affect the DEXA scan.

Date of first enrolment
01/08/2014

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospital

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)
The British Diabetic Association, 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

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?
HRA research summary			28/06/2023	No	No