ISRCTN05903336 https://doi.org/10.1186/ISRCTN05903336

Investigating a low carbohydrate/high protein diet in type 2 diabetes patients

Submission date
04/12/2013

Recruitment status
No longer recruiting

Registration date
21/01/2014

Overall study status
Completed

Last Edited
10/01/2017

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is evidence that low carbohydrate/high protein diets lead to improvements in weight, diabetic control and certain biochemical markers in patients with type 2 diabetes. This study will investigate the impact of the Dukan diet on diabetic control and a wider variety of biochemical markers than have previously been studied; this will give an indication of the safety of the diet. The aim to find out if a low carbohydrate/high protein diet leads to improvements in risk factors for heart disease and other complications in obese patients with type 2 diabetes.

Who can participate?
The study aims to recruit 32 obese males and females with type 2 diabetes mellitus, aged 18-75 from the City Walls Medical Centre, Chester, UK.

What does the study involve?
Participants will be randomly to one of two groups: one group will follow a low carbohydrate /high protein diet for eight weeks and the other 16 participants will follow a low-fat diet with 500-600kcal/day energy deficit. Participants will attend three clinic appointments during the eight week study. Dietary education will be provided at the first appointment; participants will be given instructions by a dietitian on how to follow either the low carbohydrate/high protein diet or a low-fat 500-600kcal deficit diet and written information will be provided. Adherence to the diet will be monitored at follow-up through a three day diet diary and dietary interviews. At each appointment, weight, height, waist circumference, percentage body fat and blood pressure will be measured and fasted blood samples will be taken.

What are the possible benefits and risks of participating?
The potential benefits for research participants in both study groups are an improvement in diabetic control, a reduction in weight and reduced risk of long-term complications including cardiovascular disease, renal disease and liver complications. While undertaking the study participants will benefit from more regular dietetic input and increased access to the dietitian than they would receive in standard care. There is potential burden on participants in the study due to increased contact with the dietitian, the changes in lifestyle associated with following a new diet, and the burden of completing diet diaries. There will be regular dietetic support to help participants follow the diets; the diet diary will also help with this and is an important tool

for monitoring participant compliance. The burden of increased contact will be limited as the visits will be held at the participants' normal GP surgery. The other potential risk to the participant is that associated with obtaining blood samples; this will be minimized as fully trained nurses/phlebotomists will be responsible for collecting these samples.

Where is the study run from?
The study is run by the University of Chester; appointments will take place at the City Walls Medical Centre, Chester, UK

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start at the beginning of 2014. Participants will be enrolled on the study for a period of eight weeks, and overall the study is expected to be completed at the start of 2015.

Who is funding the study?
The Dukan Organisation (http://www.dukandiet.co.uk/)

Who is the main contact?
1. Dr Sohail Mushtaq (s.mushtaq@chester.ac.uk)
2. Jennifer Saxon (jenniferssaxon@yahoo.co.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Sohail Mushtaq

Contact details
Department of Clinical Sciences and Nutrition
University of Chester
Parkgate Road
Chester
United Kingdom
CH1 4BJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pilot investigation into the effect of a low carbohydrate/high protein diet on cardiometabolic risk factors in obese patients with type 2 diabetes. An eight-week randomised controlled trial

Study objectives
Does an eight-week low carbohydrate/high protein dietary intervention lead to improvements in cardiometabolic risk factors in obese patients with type 2 diabetes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Liverpool East, 04/02/2014, ref: 13/NW/0864, amendments approved 29/08/2014

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Type 2 diabetes mellitus

Interventions
Participants will be randomly to one of two groups:
1. The intervention group will follow a low carbohydrate/high protein 'Dukan' diet for 8 weeks
2. The control group will follow a low-fat 500-600 kcal energy-deficit diet for 8 weeks

Participants will attend three clinic appointments during the 8-week study. Dietary education will be provided at the first appointment; participants will be given instructions by a dietitian on how to follow either the low carbohydrate/high protein diet or a low-fat 500-600 kcal deficit diet and written information will be provided. Adherence to the diet will be monitored at follow-up through a 3-day diet diary and dietary interviews. At each appointment, weight, height, waist circumference, percentage body fat and blood pressure will be measured and fasted blood samples will be taken.

Intervention Type

Behavioural

Primary outcome measure
Blood samples will be taken by phlebotomists/practice nurses working at the City Walls Medical Practice. They will be analysed at the Countess of Chester laboratory which is accredited by CPA (UK) Ltd. The following will be measured:
1. Fasting plasma glucose/fasting plasma insulin
2. Glycosylated haemoglobin
3. Lipid profile (total serum cholesterol, HDL serum cholesterol, fasting serum triglycerides - from these LDL cholesterol and cholesterol/HDL ratio will also be calculated)
4. Kidney function (serum creatinine and urea, eGFR will then be calculated)
5. Liver function tests (gamma glutamyl transpeptidase, alanine transaminase, aspartate aminotransferase, alkaline phosphatase, albumin, total protein, bilirubin)
6. Serum potassium, serum sodium, C-reactive protein
7. Serum ketones
8. Measures of oxidative stress (e-selectin, ICAM, vWF, MDA, 15-F2t isoprostane)

All outcomes will be measured at baseline and at 8 weeks.

Secondary outcome measures
Current secondary outcome measures as of 28/04/2014:
1. Anthropometric measures of height, weight and waist circumference, measured using methods outlined in the Manual of Dietetic Practice
2. Blood pressure

All outcomes will be measured at baseline and at 8 weeks; in addition the secondary outcomes will be measured at 4-week interim.

Previous secondary outcome measures:
Anthropometric measures of height, weight and waist circumference, measured using methods outlined in the Manual of Dietetic Practice.

All outcomes will be measured at baseline and at 8 weeks; in addition the secondary outcomes will be measured at 4-week interim.

Overall study start date
03/02/2014

Completion date
07/10/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/09/2014:
1. Male or female, aged 18-75
2. BMI 28-40 kg/m*2
3. HbA1c <86 mmol and a diagnosis of diabetes confirming to WHO guidelines
4. Stable medication at least three months prior to the study
5. Diabetes managed with Metformin or lifestyle only
6. English speaking with internet access

Previous inclusion criteria:
1. Male or female, aged 18-75
2. BMI 28-40 kg/m*2
3. HbA1c <64 mmol and a diagnosis of diabetes conforming to WHO guidelines
4. Stable medication at least three months prior to the study
5. Diabetes managed with Metformin or lifestyle only
6. English speaking with internet access

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
32

Key exclusion criteria
Current exclusion criteria as of 18/09/2014:
1. History of eating disorder
2. Currently following a restrictive diet
3. Currently taking part in other research
4. Impaired kidney function
5. Impaired liver function
6. Patients taking medications to reduce blood clots
7. Pregnant women
8. Non-English speaking
9. No internet access

Previous exclusion criteria:
1. History of eating disorder
2. Currently following a restrictive diet
3. Currently taking part in other research
4. Impaired kidney function
5. Impaired liver function
6. Patients taking medications to reduce blood clots or promote production of urine
7. Pregnant women
8. Non-English speaking
9. No internet access

Date of first enrolment

23/04/2014

Date of final enrolment
02/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Chester
Chester
United Kingdom
CH1 4BJ

Sponsor information

Organisation
University of Chester (UK)

Sponsor details
c/o Mark Helsdon
Research, Postgraduate and Knowledge Transfer Services
Parkgate Road
Chester
England
United Kingdom
CH1 4BJ

Sponsor type
University/education

Website
http://www.chester.ac.uk/

ROR
https://ror.org/01drpwb22

Funder(s)

Funder type
University/education

Funder Name
Regime Dukan (UK)

Funder Name
University of Chester (UK)

Results and Publications

Publication and dissemination plan
The results will primarily be published in a student thesis, forming part of a Masters by Research.

Intention to publish date

Individual participant data (IPD) sharing plan
The trialists do not intend to publish this study as an article as they failed to recruit the required number of subjects to reach statistical significance. As a result the data generated (other than the results summaries) will not be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		01/11/2016	10/01/2017	No	No
HRA research summary			28/06/2023	No	No