ISRCTN48034106 https://doi.org/10.1186/ISRCTN48034106

Effect of a low-carbohydrate diet on the bone and cardiovascular health in females

Submission date	Recruitment status	[ ] Prospectively registered
05/08/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/08/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/08/2015	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people start diet plans in attempts to lose weight but don't always consider whether the diet they are on will provide enough nutrients for good health. The low carbohydrate diet has become more popular as a weight loss method in recent years, but its effect on bone health is not really known.
It is well known, that when women go through the menopause, levels of the hormone oestrogen fall. This has been linked to the weakening of bone, leading to the development of conditions such as osteoporosis, where the bones become weak and fragile.
The aim of this study is to find out what the effect of eating a low-carbohydrate diet will have on bone and cardiovascular health (for example, the heart) in women going through the menopause.

Who can participate?
Women between the ages of 39 and 65, with a BMI between 25 and 30

What does the study involve?
Measurements are completed to test the participants' normal nutritional intake, as well as their bone and cardiovascular health at the start of the study. They are then randomly allocated into one of two groups. Those in group one consume a low-carbohydrate diet for six months, at which time the measurements are repeated. They then go back to their normal diet for a further six months before final measurements are taken. Those in group two consume their normal diet for six months before the measurements are repeated. They then consume a low-carbohydrate diet for six months before final measurements are taken.

What are the possible benefits and risks of participating?
Potential benefits are that participants may lose weight on the diet. They also get a report on their bone mineral density from the DXA scan as well as details of their nutrient intake.

Where is the study run from?
Waterford Institute of Technology (Ireland)

When is the study starting and how long is it expected to run for?
October 2008 to June 2011

Who is funding the study?
Institute of Technology Tallaght (Technological Sector Research Strand III Grant) (Ireland)

Who is the main contact?
Dr Lorna Doyle
lmdoyle@wit.ie

Contact information

Type(s)
Scientific

Contact name
Dr Lorna Doyle

Contact details
Dept. Health Sport and Exercise Science
Health Sciences Building
Waterford Institute of Technology
Waterford
Ireland
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of a six month low-carbohydrate diet on the biomarkers of bone and cardiovascular health in pre- and post-menopausal women: a randomised control crossover trial

Study objectives
1. Consumption of a low carbohydrate diet amongst menopausal females may result in insufficient nutrient intake to support bone health.
2. Consumption of a low carbohydrate diet may be supportive to cardiovascular health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Waterford Institute of Technology, 04/02/2010, ref: 10/HSES/03

Study design
Single-centre randomized control crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Bone and cardiovascular health

Interventions
Intervention Group: After initial measurements, participants consume a low carbohydrate diet for 6 months, followed by measurements and then resume normal diet for a further 6 months before having the measurements repeated.

Control Group: After initial measurements, participants consume their normal diet for 6 months, followed by measurements and then consume a low carbohydrate diet for 6 months before having the measurements repeated.

Intervention Type
Other

Primary outcome measure
1. The effect of nutrient intake (macro-nutrient and micronutrients measured using food diaries analysed on CompEat dietary analysis software) on bone health (bone mineral mass and density and indicators of bone formation and resorption). Serum markers of bone turnover (bone-specific alkaline phosphatase (BSAP), osteocalcin (S-OC) and C-terminal peptide of collagen type-1 (S-CTx)), insulin, IGF-1 & IGFBP-3 were all measured by Enzyme-Linked Immuno Sorbent Assay (ELISA). This was measured at 3 and 6 months.
2. . The effect of nutrient intake (macro-nutrient and micronutrients) on cardiovascular health (measured through endothelial microparticles, blood cholesterol and endothelial inflammatory biomarkers). This was measured at 3 and 6 months.

Secondary outcome measures
1. Weight loss (weight and height were recorded using an electronic balance and stadiometer) as a result of the low carbohydrate diet and net endogenous acid production (NEAP) as a result of lower carbohydrate ratio. This was measured at 3 and 6 months.

2. Net endogenous acid production (NEAP) as a result of lower carbohydrate ratio. Net Endogenous Acid Production (NEAP) was calculated based on the method described be Remer et al. (2003). This was measured at 3 and 6 months.

Overall study start date
01/10/2008

Completion date
20/06/2011

Eligibility

Key inclusion criteria
1. Females aged between 39 and 65
2. Body Mass Index (BMI) between 25 and 30

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
24

Key exclusion criteria
1. Pregnancy or lactation
2. One hormone replacement therapy
3. Currently engaging in intense physical activity
4. History of chronic menstrual irregularities
5. Have had a hystorectomy
6. Have an osteoporosis T score of less then -1
7. Those suffering from diabetes mellitus, kidney disease, chronic illness, inflammatory conditions, renal, gastrointestinal or hormonal disorders
8. Those suffering from rheumatoid arthritis, osteo-arthritis or metabolic diseases of the bone e. g. osteoporosis or Piaget’s disease
9. If the subject had engaged in dieting practices in the 6 months prior to the study (including a low carbohydrate diet)
10. Excessive smokers or alcohol drinkers
11. Taking drugs known to affect bone metabolism, other prescribed drugs such as diuretics, antibiotics, antacids and Cox-2 inhibitors

Date of first enrolment
01/05/2009

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
Ireland

Study participating centre
Waterford Institute of Technology
Department of Health Sport and Exercise
Health Sciences Building
Cork Road
Waterford
Ireland
-

Sponsor information

Organisation
Waterford Institute of Technology

Sponsor details
Dept. Health Sport and Exercise Science
Waterford Institute of Technology
Waterford
Ireland
-

Sponsor type
University/education

Funder(s)

Funder type
University/education

Funder Name
Institute of Technology Waterford (Technological Sector Research III Grant)

Results and Publications

Publication and dissemination plan

This research was presented at the Nutrition Society meeting in London Dec 2011. It is in the process of being prepared for publication for a Nutrition Society journal.

Intention to publish date
30/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request