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Choline and bone health

Submission date 11/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/01/2011	**Overall study status** Completed	
Last Edited 17/12/2012	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Osteoporosis is widely recognised as a major public health problem. The National Osteoporosis Society estimates that 1 in 3 women and 1 in 12 men in the UK will have osteoporosis over the age of 50 years. Dietary habits are factors likely to be important in influencing bone health in humans. In particular intakes of the mineral calcium and vitamin D for many years were considered to be implicated in causing the condition. However, although the effects of dietary calcium on bone have been researched extensively, there is evidence for roles of other nutrients. Evidence is now emerging to suggest that nutrients other than calcium and vitamin D are likely to affect bone health throughout the lifespan. Choline has only recently been recognised as an essential nutrient in humans. There are a number of animal studies investigating the link between choline and bone health. These studies have reported an association between choline deficiency and bone abnormalities in chickens and geese. However, to date, there has been no work carried out to investigate the role of choline in humans and bone health.
High plasma homocysteine (tHcy) levels have been linked to osteoporosis and while the cause of elevated tHcy is considered to have many causes (including genetic, nutritional and lifestyle factors), a deficiency of one or more B vitamins certainly has a role. These vitamins are involved in the breakdown and clearance of tHcy, and thus may have a protective effect against osteoporotic fracture. The purpose of this study was to improve our understanding of the relative importance of other nutrients, other than vitamin D and calcium, namely choline, riboflavin and folate in bone health.
The aims and objectives of the study were:
1. To determine if there is an interrelationship among choline, methyl donors (i.e. folate and related B vitamins), betaine and bone status in postmenopausal women.
2. To investigate the impact of dietary choline supplementation on various markers of bone health in postmenopausal women.
3. To measure the effect of choline bitartrate supplementation on tHcy, related B vitamins and serum lipids.
4. To investigate whether riboflavin/folate supplementation in participants of a particular genotype may infer a benefit on markers of bone health.

Who can participate?
Apparently healthy postmenopausal women aged between 50-70 years. Postmenopausal status was defined as the absence of a menstrual cycle for up to a year
All volunteers were screened for a full blood picture, liver function and lipid profile. Individuals

whose blood results fell outside the normal range were referred to their GP and excluded from entering the study. Other exclusion criteria included: use of vitamin B supplements, history of alcohol abuse; smoking, body mass index 30 or over; endocrine or metabolic disorders, or receiving medicine/vitamins known to influence bone heath or related B vitamin status.

What does the study involve?
This study was carried out on a sample of 43 postmenopausal women. Half of the sample (23 women) received treatment with choline bitartrate and the other half (20 women) received a dummy (placebo) pill for 12 weeks. At baseline (before they started taking the pills), 6 weeks and 12 weeks after, blood samples were taken to assess choline and B vitamin levels in their blood. Various other measures of bone health were also taken at baseline, 6 weeks and 12 weeks.

What are the possible benefits and risks of participating?
The benefits of taking part in this study consisted of the following: Full DEXA body scan which provides useful information regarding the state of their bone health and a full blood screening profile which provides participants with feedback regarding their liver function, lipid profile etc. This study posed no risks to participants heath

Where is the study run from?
The Metabolic Suite, University of Ulster, Coleraine.

When is the study starting and how long is it expected to run for?
This study ran between March 2004 and September 2004.

Who is funding the study?
Department of Employment and Learning in Northern Ireland (UK). Akzo Nobel Functional Chemicals supplied the choline supplements.

Who is the main contact?
Professor Sean Strain
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Contact information

Type(s)
Scientific

Contact name
Prof Sean Strain

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Choline supplementation in postmenopausal women: effects on bone health and risk markers for cardiovascular disease (CVD) - a randomised double-blind placebo-controlled intervention trial

Acronym
MEDIBONE

Study objectives
Dietary choline supplementation will impact favourably on surrogate biomarkers of bone health and cardiovascular disease (CVD) risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of the University of Ulster approved on the 22nd May 2002 (ref: UUREC 02/20)

Study design
Randomised double-blind placebo-controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Bone health, cardiovascular disease

Interventions
Patients are randomised to receive either 12 weeks of 2.5 g/d of choline bitartrate (1 g choline) or placebo (2.5 g/d tartaric acid). The duration of follow up was 12 weeks with volunteers sampled at baseline, week 6 and week 12.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Choline

Primary outcome measure
Choline status, measured at baseline, week 6 and week 12.

Secondary outcome measures
Measured at baseline, week 6 and week 12:
1. B vitamin and betaine status
2. Plasma homocysteine
3. Bone turnover markers

Overall study start date
01/02/2005

Completion date
01/10/2005

Eligibility

Key inclusion criteria
1. Women aged 50 - 70 years
2. Independently mobile
3. Postmenopausal (menopausal status defined as at least 6 months of amenorrhoea within the past year)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
44

Key exclusion criteria

1. Smoking
2. Body mass index (BMI) greater than 35 kg/m^2
3. Hepatic or renal disease
4. Gastrointestinal disease
5. Endocrine or metabolic abnormalities
6. Use of drugs or dietary supplements known to influence B vitamin or choline status or metabolism
7. Haematological disorder
8. Serum vitamin B-12 concentration less than 111pmol/l or serum creatinine concentration greater than or equal to 130 umol/l

Date of first enrolment
01/02/2005

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
NICHE
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
University of Ulster (UK)

Sponsor details
Cromore Road
Coleraine
Northern Ireland
United Kingdom
BT52 1SA

Sponsor type
University/education

Website

http://www.ulster.ac.uk/

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
Department of Employment and Learning in Northern Ireland (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012		Yes	No