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To determine whether taking low doses of daily folic acid and vitamin B12 capsules for 2 years can improve bone health in coeliac disease patients

Submission date
09/08/2012

Recruitment status
No longer recruiting

Registration date
11/10/2012

Overall study status
Completed

Last Edited
09/08/2017

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims:
B-vitamins, in particular folic acid and vitamin B12, may have a role in protecting bone health. Coeliac disease patients have a higher risk of both poor bone health and low B-vitamin levels. For this reason, we aim to investigate whether supplementing coeliac patients with folic acid and vitamin B12 for a 2 year time period can improve their bone health.

Who can participate?
Coeliac patients, diagnosed by endoscopy and over the age of 18.

What does the study involve?
Participants will be randomly assigned to one of two treatment groups, the placebo group (where participants take a daily placebo capsule) or the B-vitamin group (where you take a daily capsule containing folic acid and vitamin B12). The B-vitamin containing capsule and the placebo containing capsule look exactly the same so participants will not know what treatment you are assigned to. Participants will take a daily capsule for the 2 year study duration. Participants will also be invited to attend 3 appointments, one at the beginning of the 2 years, one after 1 year (i. e. half way through the study) and one at the end of the 2 year study. Each appointment will take approximately 1 hour and will involve an interview section (where participants will be asked questions about your diet, lifestyle and medical history), a measurements section (where participants height, weight, waist and hip measurements will be taken) and a blood sample (taking no more than 30mls of blood). Additionally, participants will have a DXA bone scan done at the first appointment and at the last appointment. DXA bone scans use low levels of X-rays to determine the bone mineral content, they are painless and take about 10 minutes to complete.

What are the possible benefits and risks of participating?
Any abnormal blood results and all DXA results will be sent to participants' GPs for follow-up. Participants taking the B-vitamin containing capsule, may show an improvement in bone mineral density. There are no negative side effects expected as a result of taking the daily capsule. There

is the usual the risk of bruising accompanies every blood sample, however a fully trained phlebotomist will perform all the blood sampling and every effort will be made to minimise the risk of bruising. The DXA scan involves the use of small amounts of X-rays and is considered to pose a very low risk to you.

Where is the study run from?
The study is primarily run from the University of Ulster, Coleraine. Coeliac patients were recruited through Altnagelvin Hospital and Causeway Hospital.

When is the study starting and how long is it expected to run for?
The recruitment of study participants started in August 2011 and continued for 10 months. As a result, participants will finish the 2 year study duration at staggered times. All study appointments are expected to be complete by June 2014.

Who is funding the study?
NICHE (Northern Ireland Centre for Food and Health), the Western Trust Discretionary Research Fund of the WHSCT (Western Health and Social Care Trust) and DEL (Department of Education and Learning).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A double-blind, randomised, placebo controlled trial to investigate the effect of combined folic acid (400 µg) and vitamin B12 (10 µg) supplementation for 2 years on bone mineral density within coeliac disease patients

Study objectives
It is hypothesised that the coeliac patients supplemented with combined folic acid and vitamin B12 for a 2 year period will show an improvement in bone mineral density (and thereby bone health) compared to those coeliac disease patients taking the placebo capsule.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Office for Research Ethics Committees in Northern Ireland (ORECNI), 10/05/2011
2. Western and Northern Health and Social Care Trusts, 18/05/2011 and 17/06/2011

Study design
Two-year double-blind randomised placebo 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 contact clarke-m3@email.ulster.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Coeliac disease

Interventions
Intervention arm: Folic acid (400µg) and vitamin B12 (10µg) combined in a single capsule for 2 years
Placebo: a single placebo capsule for 2 years

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Folid acid, Vitamin B12

Primary outcome measure
Bone mineral density (BMD) measured by dual energy X-ray absorptiometry

Secondary outcome measures
No secondary outcome measures

Overall study start date
18/06/2011

Completion date
29/05/2015

Eligibility

Key inclusion criteria
Coeliac disease patients diagnosed by endoscope and over the age of 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
115 participants

Key exclusion criteria
1. Pregnancy
2. Current (or recent past) B-vitamin supplementation
3. Treatment with medication known to interfere with B-vitamin metabolism
4. Liver or kidney problems
5. Other gastrointestinal conditions

Date of first enrolment
01/08/2011

Date of final enrolment

01/05/2012

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
University of Ulster
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
University of Ulster (UK)

Sponsor details
c/o Mr Nick Curry
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Newtonabbey
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Sponsor type
Not defined

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

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
Northern Ireland Centre for Food and Health (NICHE) (UK)

Funder Name
The Western Trust Discretionary Research Fund of the WHSCT (Western Health and Social Care Trust) and DEL (Department of Education and Learning; PhD studentship) (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	01/08/2015		Yes	No