

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	☐ Prospectively registered ☐ Protocol
Registration date 11/10/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/08/2017	Condition category Digestive System	☐ 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

Contact name

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Additional identifiers

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

Primary study design

Interventional

Study design

Two-year double-blind randomised placebo controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

Northern Ireland

Study participating centre

University of Ulster

Coleraine

United Kingdom

BT52 1SA

Sponsor information

Organisation

University of Ulster (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

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