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Vitamin supplementation in adult coeliac disease patients

Submission date	Recruitment status
16/03/2006	No longer recruiting
Registration date	**Overall study status**
21/04/2006	Completed
Last Edited	**Condition category**
11/01/2021	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

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

Vitamin supplementation in adult coeliac disease patients

Study objectives
Vitamin supplementation for six months will normalize biochemical markers, general well-being and gastrointestinal symptoms in adults with longstanding coeliac disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Linkoping University Ethics Committee, Linkoping, Sweden on 19/05/2004, reference number: 44/04

Study design
Randomised, double-blind, parallel, placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Adult coeliac disease under dietary treatment

Interventions
A daily dose of TrioBe® (800 µg folic acid, 500 µg cyanocobalamin, 3 mg pyridoxine) versus placebo for six months

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin supplements

Primary outcome measure
To determine if plasma total homocysteine, a marker of vitamin deficiency, could be normalized by six months of vitamin supplementation

Secondary outcome measures
To determine if psychological general well-being or gastrointestinal symptoms could be normalized by six months of vitamin supplementation

Overall study start date
15/12/2003

Completion date
28/11/2005

Eligibility

Key inclusion criteria
1. Men and women aged 45-64 yrs with a biopsy-proven coeliac disease treated for at least 8 years and in proven remission
2. Declaration of keeping a strict gluten free diet
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
65

Total final enrolment
65

Key exclusion criteria
1. Concomitant serious disease
2. Hypersensitivity to B-vitamins
3. Positive coeliac disease serology
4. Unable to comply with protocol
5. Previous small intestinal resection
6. Vitamin supplementation during last three months
7. Concomitant phenobarbital, phenytoin, methotrexate and/or trimethoprim

Date of first enrolment
15/12/2003

Date of final enrolment
28/11/2005

Locations

Countries of recruitment
Sweden

Study participating centre
NSÖ stab
Norrköping
Sweden
S-601 82

Sponsor information

Organisation
Recip AB (Sweden)

Sponsor details
7 Lagervägen
Haninge
Sweden
S-136 50

Sponsor type
Industry

Website
http://www.recip.se

ROR
https://ror.org/01apnjb23

Funder(s)

Funder type
Industry

Funder Name
Recip AB

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	15/04/2009	11/01/2021	Yes	No