

Vitamin supplementation in adult coeliac disease patients

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
16/03/2006	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
21/04/2006	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
11/01/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Claes Hallert

Contact details

NSÖ stab
Vrinnevisjukhuset
Norrköping
Sweden
S-601 82

Additional identifiers

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/01apnjb23>

Funder(s)

Funder type

Industry

Funder Name

Recip AB

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