Effect of AN-PEP enzyme on the effects of gluten ingestion in patients with coeliac disease

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26422

Source
NTR

Brief title
N/A

Health condition

Celiac disease patients

Sponsors and support

Primary sponsor: DSM Food Specialties
Source(s) of monetary or material Support: DSM Food Specialties

Intervention

Outcome measures

Primary outcome

Immunohistopathological changes in small intestinal biopsies to diagnose coeliac disease

Secondary outcome

- Gluten reactive T cells

- Coeliac disease specific antibodies

- Coeliac disease-associated clinical symptoms (questionnaire) to diagnose coeliac disease

Study description

Background summary

Rationale:

Coeliac disease is an autoimmune disorder of the small bowel and is caused by a reaction to a gluten protein found in wheat. Gluten proteins are resistant to degradation in the gastrointestinal tract.

The AN-PEP enzyme was shown to degrade gluten in an in vitro digestion model.

Objectives:

Determine whether AN-PEP enzyme is effective in mitigating the effects of gluten ingestion in patients with celiac disease

Study Design:

Randomised double-blinded semi-cross-over design

Patients:

Fourteen patients with coeliac disease, 18-70 years old

Treatments:

This study consists of three 14-d periods.

Period 1: Patients are given a food product containing 8 g of wheat protein, to which AN-PEP is added, once daily for 14 d.
Period 2: Wash-out period of 14 d. During this period patients will consume a gluten-free diet.

Period 3: Patients who are negative for coeliac disease symptoms during the 1st period will be randomised across two groups. Both groups receive a food product containing 8 g of wheat protein once daily for 14 d. One group receives additional AN-PEP with the gluten meal whereas the other groups receives the placebo.

- Primary study parameters:

Small intestinal biopsy material will be analysed for the following:

1. Histopathological changes according to the Modified Marsh criteria

2. The presence and activity of gluten reactive T cells isolated from biopsies

3. The immunophenotype of lymphocytes (IEL and LPL) isolated from biopsies

- Secondary study parameters:

Peripheral blood samples will be analysed for the following:

1. The presence and activity of gluten reactive T cells

2. The presence of coeliac disease specific antibodies (EMA, tTGA)

3. The presence of coeliac disease- associated clinical symptoms based on a quality of life questionnaire

Study objective

Determine whether AN-PEP enzyme is effective in mitigating the effects of 8 g wheat protein ingestion in patients with celiac disease

Study design

Before and after 2-week intake period

Intervention

Patients will consume 8 g wheat protein daily with AN-PEP enzyme for 14 d. After a 14-d washout period, patients who are negative for coeliac disease symptoms during the 1st period will randomly receive 8 g wheat protein daily with AN-PEP enzyme or placebo for another 14 d.

Contacts

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Eligibility criteria

Inclusion criteria

1. Confirmed diagnosis of coeliac disease (Marsh III B/C) ; that means crypt hyperplasia and subtotal or total villous atrophy, while using a normal diet followed by normalisation and clinical improvement on a gluten-free diet.

2. Detectable coeliac disease specific antibodies (EMA, tTGA) at time of diagnosis.

3. A strict gluten free diet for at least 1 year and normalised villous architecture (Marsh 0/I).

4. Male and female, 18-70 years old.

5. No detectable anti-endomysium and low anti-tissue transglutaminase (<4 U/ml) prior to the start of the study.

6. Patient is willing to undergo all protocol related assessments and visits (including up to 3 separate oesophago-gastro-duodenoscopies with multiple biopsies taken each time from the descending duodenum.

7. Patient has read the information provided on the study and given written consent;

8. Female participants at fertile age must use adequate contraception.

Exclusion criteria

1. Use of any immunoregulatory drug within the last 6 months

2. Use of any anticoagulant drug

3. Clinically suspected bleeding tendency

4. Pregnancy or breast feeding

5. Presence of any concurrent active infection

6. IgA deficiency

7. Use of medication within 8 hour prior to intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-05-2008
Enrollment:	14
Type:	Actual

Ethics review

Positive opinion

Date:	18-04-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1236
NTR-old	NTR1281
Other	: 20080328-ANP
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A