Effect of AN-PEP enzyme on gluten digestion.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21404

Source Nationaal Trial Register

Brief title AN-PEP-02

Health condition

Healthy subjects. Intended target population; gluten intolerant/sensitive people

Sponsors and support

Primary sponsor: Dr Maaike Bruins DSM Biotechnology Centre Alexander Fleminglaan 1 2613 AX Delft, The Netherlands +31 15 2792056 Maaike.Bruins@DSM.com Source(s) of monetary or material Support: DSM

Intervention

Outcome measures

Primary outcome

Effect AN-PEP with a low or high caloric meal on duodenal gluten epitope exposure.

Secondary outcome

Effect AN-PEP with a low or high caloric meal on:

- 1. Gastric gluten concentrations and AUC over time;
- 2. Gastric and duodenal pH;
- 3. Gastric half emptying time;

4. Gastric and duodenal gluten concentrations or absolute amounts over time related to 3 and 4.

Difference in means between a low and high caloric meal with AN-PEP in:

1. All endpoints mentioned above.

Study description

Background summary

In this trial, the effect of AN-PEP enzyme on gastrointestinal breakdown of gluten will be investigated in healthy subjects. In addition, it will be assessed if meal calories can affect the efficacy of AN-PEP. Subjects receive intragastrically, either AN-PEP or placebo with either a high or a low caloric meal in a double-blind, randomized, placebo-controlled, cross-over fashion. Gastrointestinal fluid will be sampled to measure breakdown of gluten.

Study objective

AN-PEP helps to digest gluten in vivo.

Study design

N/A

Intervention

All subjects will come to the study site for 4 test days. A gastro-duodenal catheter will be placed in the stomach and duodenum under x-ray control.

At these test days, in a crossover fashion, all subjects receive enterally via this catheter one of the following treatments:

- 1. A low caloric gluten meal together with AN-PEP drink;
- 2. A high caloric gluten meal together with AN-PEP drink;
- 3. A low caloric gluten meal together with placebo drink;
- 4. A high caloric gluten meal together with placebo drink.

The subjects will be randomised before start in a double-blind fashion in blocks of four. Meals contain 5.2 g gluten powder (4 g gluten protein) which is mixed in all test meals (300 mL). The low and high caloric meals differ in fat and carbohydrate. The meal is co-infused with AN-PEP or placebo in 50 mL water. Stable 13C-octanoic acid is added to the meals to measure gastric emptying rate.

Contacts

Public

Maastricht University Medical Center, Department of Internal Medicine, Division of Gastroenterology-Hepatology P.O. Box 5800 Ad Masclee Debeijeplein 25 Maastricht 6202 AZ The Netherlands +31 (0)43 3875021 Scientific Maastricht University Medical Center, Department of Internal Medicine, Division of Gastroenterology-Hepatology P.O. Box 5800 Ad Masclee Debeijeplein 25 Maastricht 6202 AZ The Netherlands +31 (0)43 3875021

Eligibility criteria

Inclusion criteria

- 1. Male/female;
- 2. Age ≥18 but <45 yr;
- 3. Hormonal contraceptive treatment;
- 4. Subject is willing to undergo all protocol related assessments;

5. Subject has read and understood the information provided on the study and given written informed consent.

Exclusion criteria

Any medical condition or laboratory test result that in the opinion of the investigators may interfere with the study and may jeopardise the health status of the participant.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	30-04-2011
Enrollment:	12
Туре:	Anticipated

Ethics review

Not applicable Application type:

Not applicable

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	NL2652
NTR-old	NTR2780
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results N/A