Bioavailability of phosphorus after oral intake of hypoallergenic infant formula with additional phosphate sources in healthy adult volunteers with a neutral stomach pH.

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This study's objective is to assess the bioavailability of phosphorus after oral intake of a new hypoallergenic infant formula compared to the bioavailability of phosphorus after oral intake of the current hypoallergenic infant formula.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON46664

Source
ToetsingOnline

Brief title
UP

Condition

- Allergic conditions

Synonym
Cow□s milk allergy

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research BV

Intervention

Keyword: Bioavailability, Hypoallergenic, Infant formula, Phosphorus

Outcome measures

Primary outcome

The primary outcome parameter in this study is the serum P AUC 0-360

[mmol/L*min] (product A compared to product B).

Secondary outcome

The secondary outcome parameters in this study are comparisons of product A and

B on:

- Serum P [mmol/L] (product A - B), Cmax, iCmax [mmol/L], Tmax [min]

- Serum Ca [mmol/L] (product A - B), Cmax, iCmax [mmol/L], AUC0-360

[mmol/L*min], iAUC0-360 [mmol/L*min], Tmax [min]

- Serum creatinine [µmol/L] (product A - B), Cmax, AUC0-360 [µmol/L*min], Tmax

[min]

- Serum iPTH [pmol/L] (product A - B), Cmax, AUC0-360 [pmol/L*min], Tmax [min]

- Serum AP [U/L] (product A - B), Cmax, AUC0-360 [U/L*min], Tmax [min]

- Urinary P [mmol/L] (product A - B), Cmax, iCmax [mmol/L], AUC0-370

[mmol/L*min], iAUC0-370 [mmol/L*min] and Tmax [min]

- Urinary Ca [mmol/L] (product A - B), Cmax, iCmax [mmol/L], AUC0-370

[mmol/L*min], iAUC0-370 [mmol/L*min] and Tmax [min]

- Urinary creatinine [mmol/L] (product A - B), Cmax, AUC0-370 [mmol/L*min] and

Tmax [min]

Study description

Background summary

Cow*s milk allergy is the most common food allergy in infancy, affecting up to 5% of infants in their first year of life. For these children hypoallergenic infant formula is available on the market, which decreases the chance of allergic reactions. This hypoallergenic infant formula is also provided to infants in medically complex patients in this age group, in combination with medication and via different routes of administration. To optimize the uptake of minerals of the current hypoallergenic infant formula for all target groups using the formula, additional sources of phosphate have been added to the formula. In this study the uptake of these minerals will be compared between the two products.

Study objective

This study's objective is to assess the bioavailability of phosphorus after oral intake of a new hypoallergenic infant formula compared to the bioavailability of phosphorus after oral intake of the current hypoallergenic infant formula.

Study design

This is a randomised, double-blind, crossover, single-centre, single-dose study

Intervention

In this study two study products will be investigated:
- Product A: New hypoallergenic infant formula in one serving
- Product B: Current hypoallergenic infant formula in one serving

Study burden and risks

Subjects should take a total volume of ~475 ml of study product mixed with water and flavoring during 2 visits. 4 days before visits 1 and 2 the subjects should start esomeprazole intake at home. On the day before the visits, subjects should not eat/drink food high in phosphorus and they have to come fasted to the research center in the evening for intake of esomeprazole.

Afterwards, subjects eat a standardized diner. During the whole study period subjects should take a daily dose of 10 µg vitamin D. At visits 1 and 2 a nasogastric tube is placed and subjects should take again a dose of esomeprazole, at several time points blood will be sampled, urine will be collected, stomach pH assessed, and a short questionnaire should be completed. Furthermore, a pregnancy test will be performed for women 3 times in total (using a urine dipstick). During participation, subjects should adhere to a number of rules related to medication- and supplement use and lifestyle.
Because the study will be performed in healthy adult volunteers and the product that is being tested is normally safely used in a vulnerable population (namely infants with food allergy), no severe adverse events are expected. However, subjects may suffer from e.g. bloating and abdominal distention due to the fact that the product is taken in a concentrated form. The risks of the other study procedures are low and these will be performed / guided by qualified study staff.
The burden for participants in this study is considered small and the benefits of obtaining more knowledge on phosphorus and calcium absorption after intake of the formula intended for use in children on a milk-free diet outweighs the minimal burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age * 18 and * 40 years
- Non-Asian race*
- Body Mass Index (BMI) * 18.5 and * 24.9 kg/m2
- Willingness and ability to comply with the protocol
- Willingness to use a method of birth control during participation in the study (women only)
- Written informed consent
- Judged by the investigator to be in good health;*Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Exclusion criteria

- Any medical condition that interferes significantly with digestion and/or gastrointestinal (GI) function (e.g. inflammatory bowel disease, gastroesophageal reflux disease, diaphraghma hernia or diaphraghma surgery, gastric ulcer, gastritis, (gastro)enteritis, gall bladder problems, pancreatitis, GI cancer, oesophageal and/or gastric surgery)
- Known renal or hepatic failure or known thyroid dysfunction
- Any known food allergy and/or food intolerance
- Any ongoing cancer (except for basal cell carcinoma) and/ or cancer treatment
- Serum 25(OH)D of < 50 nmol/l
- Haemoglobin in men <7.5 mmol/l and in women <7.0 mmol/l
- Use of any medication within 3 weeks of screening except for oral contraceptive and incidental use of paracetamol and/or nonsteroidal anti-inflammatory drugs (e.g. ibuprofen and aspirin)
- Known hypersensitivity to esomeprazole, and fructose-intolerance, glucose-galactose malabsorption, sucrase-isomaltase insufficiency
- Use of nutritional supplements (other than vitamin D) within two weeks of Visit 1
- Unsuccesfull placement of a cannula for taking blood samples at Visit 1

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-01-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-05-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL63221.056.17