UP2-study

Gepubliceerd: 26-10-2018 Laatst bijgewerkt: 18-08-2022

The hypothesis formulation for the primary outcome parameter is: - H0: The effect of using product A is unequal to the effect of using product B with respect to serum P AUC0-360 [mmol/L*min] in subjects with elevated gastric pH. - H1: The effect...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25128

Bron
Nationaal Trial Register

Verkorte titel
UP2

Aandoening

None: healthy volunteers

Ondersteuning

Primaire sponsor: Nutricia Research
Overige ondersteuning: Nutricia Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter in this study is serum P AUC0-360 [mmol/L*min] (product A compared to product B).

Toelichting onderzoek

Achtergrond van het onderzoek

This randomised, double blind, cross-over single-centre, single-dose study is designed to assess the bioavailability of phosphorus after oral intake of two hypoallergenic infant formula in healthy adult volunteers with a neutral stomach pH.

Doel van het onderzoek

The hypothesis formulation for the primary outcome parameter is:

- H0: The effect of using product A is unequal to the effect of using product B with respect to serum P AUC0-360 [mmol/L*min] in subjects with elevated gastric pH.

- H1: The effect of using product A is equal to the effect of using product B with respect to serum P AUC0-360 [mmol/L*min] in subjects with elevated gastric pH.

Onderzoeksopzet

V1 (day 1), V2 (day 7)

Onderzoeksproduct en/of interventie

Duration of intervention: 2 weeks

- Product A: New hypoallergic infant feeding one serving

- Product B: Comparable hypoallergic infant feeding one serving

Contactpersonen

Publiek

Nutricia Research
PO Box 80141

Monique Visser

Utrecht 3508 TC
The Netherlands

+31 30 2095 000

Wetenschappelijk

Nutricia Research
PO Box 80141

Monique Visser

Utrecht 3508 TC
The Netherlands
+31 30 2095 000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 18 and ≤ 40 years

- Body Mass Index (BMI) ≥ 18.5 and ≤ 24.9 kg/m2

- Non-Asian race*

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Any medical condition that interferes significantly with digestion and/or gastrointestinal (GI)

function (e.g. inflammatory bowel disease, gastroesophageal reflux disease, celiac disease, diaphraghma hernia or diaphraghma surgery, gastric ulcer, gastritis, (gastro)enteritis, gall bladder problems, pancreatitis, GI cancer, oesophageal and/or gastric surgery), in opinion of the investigator

- Known renal or hepatic failure or known thyroid dysfunction

- Any known food allergy and/or food intolerance for: cow’s milk, lactose, peanuts, nuts, wheat, soy, potato, carrot, onion, tomato, corn, apple and/or orange

- Any ongoing cancer (except for basal cell carcinoma) and/ or cancer treatment

- Serum 25(OH)D of < 50 nmol/l at screening

- Haemoglobin (Hb) in men <7.5 mmol/l and in women <7.0 mmol/l at screening- Use of any medication within 1 week of Visit 1 except for oral contraceptive, incidental use of paracetamol and/or nonsteroidal anti-inflammatory drugs (e.g. ibuprofen and aspirin) and/or common cold relievers (e.g. nasal sprays containg xylometazoline and sore throat relievers), if medically justified in opinion of the investigator

- 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

- Unsuccessful placement of a cannula for taking blood samples at Visit 1.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland
Status: Werving gestopt

(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	36
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	26-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7367
NTR-old	NTR7575
Ander register	Stichting BEBO : MPR18TA20887

Resultaten

Samenvatting resultaten
https://www.sciencedirect.com/science/article/pii/S0271531720305698