UP-study

Gepubliceerd: 27-11-2017 Laatst bijgewerkt: 18-08-2022

The hypothesis formulation for the primary outcome parameter is: -H0: The effect of using test product (Product A) is equal to the effect of using control product (Product B) with respect to the area under the curve (AUC(0-360))of serum P. -H1:...

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

Samenvatting

ID

NL-OMON25579

Bron
Nationaal Trial Register

Verkorte titel
UP

Aandoening

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 the serum P AUC(0-360) [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 a new hypoallergenic infant formula compared to the bioavailability of phosphorus after oral intake of the current hypoallergenic infant formula.

Doel van het onderzoek

The hypothesis formulation for the primary outcome parameter is:

-H0: The effect of using test product (Product A) is equal to the effect of using control product (Product B) with respect to the area under the curve (AUC(0-360))of serum P.

-H1: The effect of using test product (Product A) is unequal to the effect of using control product (Product B) with respect to the area under the curve (AUC(0-360)) of serum P.

Onderzoeksopzet

V1 (day 1), V2 (day 7)

Onderzoeksproduct en/of interventie

Duration of intervention: 2 weeks

- Product A: New hypoallergenic infant formula in one serving

- Product B: Current hypoallergenic infant formula in one serving

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

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, 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

- 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:	12-12-2017
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	27-11-2017
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	NL6680
NTR-old	NTR6850
Ander register	Protocolnummer Nutricia Research : MPR17TA15103

Resultaten

Samenvatting resultaten
No