Effects of infant formula containing milk fat on the parameters of digestion

Gepubliceerd: 07-06-2018 Laatst bijgewerkt: 18-08-2022

4 weeks of consumption of an infant formula containing milk fat reduces calcium soap formation compared to the reference formula.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26018

Bron
NTR

Verkorte titel
Optimus

Aandoening

This study is performed with healthy infants;

infant formula; digestion, comfort, calcium soap formation, milk fat;

Ondersteuning

Primaire sponsor: FrieslandCampina
Overige ondersteuning: FrieslandCampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint

The primary endpoint in this study is the total fatty acid-calcium soap excretion, at the end of each 4 weeks period of consumption, measured as mg fatty acid-calcium soaps/kg of dry weight (dw) fecal matter

Toelichting onderzoek

Achtergrond van het onderzoek

The study will be carried out by Biofortis (CRO) and it will be located in Saint Herblain, France.

Doel van het onderzoek

4 weeks of consumption of an infant formula containing milk fat reduces calcium soap formation compared to the reference formula.

Onderzoeksopzet

Infants will attend up to 4 visits :

- The selection visit (V0) is planned from birth to 2 months old.

- The randomization visit (V1) is 1 week after V0. After randomization (stratified on age at inclusion), the infant will consume whether the tested product or the reference formula for 4 weeks.

- The infant will come back after 4 weeks after starting the formula (V2) and will start consuming the other formula for 4 weeks.

- The last visit is planned following the second period of 4 weeks consumption (V3).

Onderzoeksproduct en/of interventie

After randomization, the subjects will consume the infant formulas during 2 periods of 4 weeks.

Infants will attend up to 4 visits :

- The selection visit (V0) is planned from birth to 2 months old.

- The randomization visit (V1) is 1 week after V0. After randomization (stratified on age at inclusion), the infant will consume whether the tested product or the reference formula for 4 weeks.

- The infant will come back after 4 weeks after starting the formula (V2) and will start consuming the other formula for 4 weeks.

- The last visit is planned following the second period of 4 weeks consumption (V3).

Stools samples will be collected at V1, V2 and V3 visits.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

I1. Good general health with in the opinion of the investigator: no clinically significant and relevant abnormalities of medical history or physical examination;

I2. Age between birth and 2 months (limits included);

I3. Full term infant (37 weeks ≤ gestational age ≤ 42 weeks);

I4. 2500g ≤ birth weight ≤ 4500g;

I5. Exclusively bottle-fed for at least one week at time of enrolment and only if parent(s) / guardian(s) independently decided before enrolment to exclusively bottle-feed;

I6. Having obtained both parent's or legally authorized representative's written consent in accordance with legal requirements;

I7. Parent(s) / guardian(s) who agree not to start complementary feeding during study period;

I8. Two legal representatives (parent(s) / guardian(s)) who are capable of and willing to comply with the protocol;

I9. At least one of the legal representatives is affiliated with a social security scheme.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

E1. Significant pre-natal and/or serious post-natal disease (per investigator's medical decision);

E2. Subject under antibiotics treatment at time of enrolment or infant who was under antibiotics treatment until one week prior to V0;

E3. With a known or suspected cow milk protein allergy (CMPA) or family medical history of CMPA;

E4. With a known intolerance or hypersensitivity to any of the study products' ingredients;

E5. Exposure to probiotics (any product);

E6. Minor parent(s) (below 18 years old);

E7. Infants whose parent(s) / guardian(s) cannot be expected to comply with study procedures;

E8. Currently participating or having participated in another clinical trial since birth;

E9. Parent(s) / guardian(s) presenting a psychological or linguistic incapability to sign the informed consent;

E10. Parent(s) / guardian(s) impossible to contact in case of emergency.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-06-2018
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	NL7047
NTR-old	NTR7252
Ander register	PEC17306 : Internal protocol number

Resultaten