Consumer Survey Mexico

Published: 11-06-2019
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The different processing of formulas will have an effect on stool characteristics such as consistency, frequency, amount and colour.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON20559

Source
NTR

Brief title
TBA

Condition

- Gastrointestinal signs and symptoms

Health condition

NA

Research involving
Human

Sponsors and support

Primary sponsor: FrieslandCampina
Source(s) of monetary or material Support: FrislandCampina

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Primary objective: To investigate the effect of Friso formulas on stool characteristics such as consistency, frequency, amount and colour, compared to competitors.

Secondary outcome

To measure the duration and frequency of crying, measured by the use of a crying diary

Study description

Background summary

This is an eight-day cross-sectional clinical trial meant to investigate the effect of currently consumed infant formulas with different composition, on the gut comfort in infants. A total of 400 subjects, will have the following information collected to asses protein digestion and absorption parameters: • Stool characteristics, using the Amsterdam Infant Stool Scale • Crying Diary • Gastrointestinal symptoms, using a Subject Diary and Questionnaire on Infant/Toddler Gastrointestinal symptoms, IGSQ • Socio economic information using a Socio-Economic Status questionnaire • Fecal samples will be collected during the study to allow for future analysis of relevant parameters of protein digestion and absorption. These parameters will be selected based on primary outcomes analysis.

Study objective

The different processing of formulas will have an effect on stool characteristics such as consistency, frequency, amount and colour.

Study design

8 days study - data collected each day

Intervention

There is no intervention, this is an observational study of infants habitually using different commercially available infant formulas

Contacts

Public
FrieslandCampina
Carlijn Maasakkers
Scientific
FrieslandCampina
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Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Babies and toddlers (28 days-23 months)

Inclusion criteria

(i) Term infants (gestational age > 37 weeks and < 42 weeks). (ii) Between 1- 4 months of age without weaning food intake. (iii) Birth weight of 2.5 – 4kg. (iv) Exclusively formula fed. (v) Feeding on the current formula at least 3 weeks prior to the study week. (vi) Infant cared for at home by one or two primary caregivers (parents, legal guardians, etc) who can oversee and record all activity related to data collection. (vii) Parents/caregivers agree to offer (or have offered) no additional food (other than water) over the course of the study and 48 hours before initiation of data collection. (viii) Consenting parent/legal guardian > 18 years old. (ix) Reporting parent fluent in Spanish (language of study). (x) Parents/caregivers own a smartphone and have 24-hour internet connection availability. (xi) At least one of the caregivers should be able to check their email accounts using their smartphone, and successfully download the ClaimIt app during the Screening visit.

Exclusion criteria

(i) Breastfed within 3 weeks prior to start of study. (ii) Switched formula within 3 weeks prior to start of the study. (iii) Any complimentary feeding. (iv) Weight-for-length (WFL) above 85th or under 5th percentiles at birth. (v) Congenital condition and/or previous or current illness that, according to the medical judgement of the PI, could interfere with study. These include, but are not limited to; GI tract or metabolic diseases that affect the digestion process and/or confort of the subjects. (vi) Known or increased risk of cow’s milk allergy and/ or lactose intolerance (i.e. one of the biological parents and or siblings diagnosed with cow’s milk allergy, asthma, fever, etc.). (vii) Current participation in another survey or clinical trial. (viii) Investigator's uncertainty about the willingness or ability of the /caregivers to comply with the protocol requirements (eg. Internet availability, use of technology, compliance with study visits, filling in of diaries and waiting until finishing the study to introduce weaning foods,

etc). (ix) Use of antibiotics and/or medication that, based on the investigator´s judgement, treats/cause GI symptoms and appetite changes, as well as probiotic and/or prebiotic supplements (other than those found in the formula itself) at the time of screening and/or two weeks prior to the start of the study.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2019
Enrollment:	400
Type:	Actual

IPD sharing statement

Plan to share IPD: No

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	NL7805
Other	CRO: SPRIM Mexico : Friso01

Study results

Results posted: 18-12-2023

Actual enrolment: 342

First publication
15-12-2023

URL result
Naam
BMC Pediatrics
URL