Comfort Next study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21195

Source
NTR

Brief title
Comfort Next

Health condition

functional constipation, toddlers

Sponsors and support

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Sergio Díaz madero GI Pediatrician: UNIDAD DE PEDIATRÍA S.C. (Pediatric Private Partnership)whose address is at AV. EJERCITO NACIONAL 613, INT 303. COLONIA GRANADA. 11520, MIGUEL HIDALGO. MEXICO CITY (CDMX), MEXICO
Source(s) of monetary or material Support: FrieslandCampina

Intervention

Outcome measures

Primary outcome

Difference in maintenance of good digestion measured as normal stool consistency in toddlers who were diagnosed and received medical treatment for functional constipation.

The difference will be measured as the % of total reported hard stools (stool consistency) (Bristol Stool Chart I & II) between study groups consuming different Comfort YCF products

Secondary outcome

a) Stool frequency (as number of defecations per week)

b) GI tolerance questionnaires QPGS-RIII section E – once a week

c) % of subjects reporting any hard stools

d) Modified crying diary, reluctance to defecate/go to potty or toilet- questions will be added to the Bristol stool chart to provide information if defecation was painful and if child was crying/avoiding etc.

e) number of doctor's visits of child in intervention period, number of prescribed laxatives in intervention period (as a measure of relapse).

Study description

Background summary

Overall gastrointestinal disorders (FGIDs) are very frequent in the infancy and early childhood, and even if mostly they are transient and do not require a medical treatment, they may be very distressing to a new parent as well as a child. Functional constipation is the most common FGiD above 12 months of age and peaks when the toilet training starts.

The prevailing consensus among experts is that a functional constipation in children should not be treated with diet but once constipation occurs it should be treated with pharmacological means. However experts also agree that proper balanced diets with special focus on nutrients such as: fibers and fluid intake, should be an integral part of the maintenance therapy as well as a prevention of constipation.

This study aims to examine how Friso Comfort Next: GUM (Growing UP Milk) formula is performing in supporting the maintenance of good digestion in toddlers experiencing the most common for this age group gastrointestinal disorder (FGID): constipation; against comparable comfort product of a competitor.

In a parallel open label study with commercial product Total Comfort 2 as a control/comparison, and Friso Comfort Next, otherwise healthy toddlers (12 till 32 months of age) referred to a paediatrician/ paediatric gastroenterologist with a functional constipation (diagnosed based on Rome III criteria), after standard medical treatment for constipation will receive two different Comfort Formulation.

Difference in maintenance of good digestion measured as normal stool consistency in toddlers will be the primary outcome of the study. The difference will be measured as the % of total reported hard stools (stool consistency) (Bristol Stool Chart I & II) between study groups consuming different Comfort GUM products

The Secondary Outcomes will be as follows:

a) Stool frequency (as number of defecations per week).

b) GI tolerance questionnaires QPGS-RIII section E – once a week.

c) % of subjects reporting any hard stools.

d) Modified crying diary, reluctance to defecate/go to potty or toilet- questions will be added to the Bristol stool chart to provide information if defecation was painful and if child was crying/avoiding etc.

e) number of doctor's visits of child in intervention period, number of prescribed laxatives in intervention period (as a measure of relapse).

Study objective

Group receiving Friso Comfort Next (with milk fat and mixture of different length prebiotics) will have a lower % of all hard stools reported during the 2-mo study period compared to another Young Child Formula (with partially hydrolysed whey protein, HMO, FOS, low lactose, no palm oil).

Study design

V0 - diagnosis with constipation, followed by standard pharmacological treatment, info about the study

V1 - (1 week), recruitment, signed ICF, baseline evaluation

V2; V3; V4 - every two weeks, home visits, filling in questionnaires

V5 - 8 weeks - end visit, final evaluation

Intervention

The screening of children for the identification and recruitment of eligible ones will be conducted during the visit to a paediatrician related to experiencing hard stools and constipation. Toddlers who are diagnosed with constipation according to Rome III criteria will undergo a medicinal treatment as prescribed by their physician/paediatrician for constipation. The study will start after the treatment of the acute problem has been finished,

constipation resolved and laxative decreased to the maintenance levels. The laxatives in decreasing dose will be provided during the first month of the study. During the second month there will be no laxatives provided, unless necessary due to relapse, which then will be considered as one of the outcomes parameters.

All toddlers meeting the inclusion criteria will be invited to join the study. After receiving the patient information file as well as the explanation of the trial objectives and set up, legal guardians of the children will be ask to sign informed consent form. All participants will also receive an information file on importance of proper intake of fluids and fibre rich foods for maintenance of the normal stool consistency. All participating toddlers will be randomly allocated to receive either Friso Comfort Next or another Comfort formula for the period of 2 months, which they will consume according to standard feeding tables provided by the respective manufacturer. During the intervention period parents will be asked to monitor the child's digestion (stool consistency, defecation frequency) and digestive comfort parameters (comfort questionnaires, crying diaries) with use of different questionnaires and diaries. No biological samples will be collected at any time during this study. Number of doctors' visits, their purpose and prescribed medication will also be registered. Overall anthropometric (body weight and length) measures will be collected at the beginning and end of the study.

Contacts

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Eligibility criteria

Inclusion criteria

Otherwise healthy toddlers with functional constipation (12 months till 32 months of age) – referred to a paediatrician, after standard medical treatment for constipation based on Rome III criteria's

• Full-term, healthy toddlers (born at gestational age ≥37 weeks).

• "Appropriate for gestational age" birthweight (i.e. 10th centile ≤ Birth weight ≤ 90th centile).

• Age at enrolment: between 12 months and 32 months

• Formula fed toddlers before and during the entire intervention period.

• Parents willing to sign the written informed consent

• Toddlers with a history of hard stools, for that reason referred to a paediatrician/ paediatric gastroenterologist,

• Toddlers with functional constipation – based on Rome III criteria - after standard medical treatment for constipation with PEG (Poyethylene Glycol) 1,5g/kg of body weight.

Exclusion criteria

• Severe acquired or congenital diseases, mental, metabolic or physical disorders, any symptoms of allergy (including cow's milk allergy [CMA]).

• No parents or siblings with documented CMA, diagnosed by a doctor.

• Diagnosed gastrointestinal diseases (e.g. celiac disease, Hirschsprung disease etc.) with exception of constipation

• Unwillingness to stop the use of supplements with fibers, probiotics and prebiotics two weeks before and for the duration of the study.

• Considered to be non-responder, i.e. more than 5x unsuccessful treatment with laxatives.

• Use of medication(s) known or suspected to affect fat digestion, absorption and/or metabolism; nutritional supplements; suppositories; medication that may suppress or neutralize gastric acid secretion and gut mobility at the time of screening or at any time

throughout the study period (these children will be considered as drop-outs).

• Participation in another clinical trial.

• Breast feeding 1 month before study enrollment

• Perceived lactose intolerance

• Constipation attributable to organic or anatomic causes

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	96
Type:	Anticipated

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	NL7420
NTR-old	NTR7653
Other	: LLCN00

Study results