

Investigation of the impact of Bi2muno (Bi2GOS), a novel galacto-oligosaccharide mixture, on the composition of the infant faecal microbiota

Submission date 03/01/2006	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
Registration date 23/01/2006	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 19/02/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

It is well established that formula-fed infants harbour a distinctive gastrointestinal (GI) microbiota (collection of bacteria indigenous to the infant gut) compared with those of breast-fed infants.

In general breast-fed infants' GI microbiota comprises predominately bifidobacteria, whilst formula-fed infants harbour a more diverse microbiota co-dominated by bacteroides, bifidobacteria and clostridia. Breast-feeding is, of course, considered the "gold standard" for infant nutrition. As well as supplying the necessary nutrients, breast milk confers numerous bioactive components, which afford protection of the infant (some of which may reflect the bifidobacterial predominance).

Indeed, breast-feeding is associated with reduced incidence of GI disorders (such as constipation, abdominal bloating and diarrhoea), compared with formula-feeding. Coupled with the recognized health and well-being associated with breast-fed infants, the predominance of the bifidobacterial group has generated a vast interest in improving this component of formula-fed infants' gut microbiota. Fortification of infant formulae with functional food supplements, namely probiotics (live microbial fed supplements) and prebiotics (substrates which selectively stimulate specific bacteria), has thus become a topic of particular interest.

The main objective for improving infant formulae is to better reflect the composition of breast-milk and to minimise the distinctions between breast-fed and formula-fed infants (physiological, microbiological and/or overall health status).

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved in December 2005.

Study design

Double-blind, randomised, placebo-controlled, parallel study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Infant formula

Interventions

Bi2muno (Bi2GOS) 3 g versus Placebo (Maltodextrin 3 g)

Determine the effect of Bi2muno feeding (3 g/day) on the bifidobacterial component of formula-fed infants' faecal microbiota. A double-blind, randomised, placebo-controlled, parallel design 1-month feeding study will be performed using exclusively milk-fed infants aged 8 to 10 weeks, at inclusion. Faecal samples will be collected from soiled nappies of each individual on four separate occasions: 2 at baselines (i.e. prior to commencement of the trial) and 2 post-feeding. The bifidobacterial component of the faecal microbiota will be examined for all samples, both quantitatively (using Fluorescence *in situ* Hybridization [FISH]) and qualitatively (using Denaturing Gradient Gel Electrophoresis [DGGE], a molecular profiling technique). Comparisons will be made between baseline and post-feeding samples to identify changes in the bifidobacterial microbiota over time. Also, comparisons will be made between the two feeding groups to determine the effect of Bi2muno on bifidobacterial predominance and diversity.

Updated 19/02/2014: the trial was stopped due to poor recruitment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bi2muno (Bi2GOS) 3 grams Placebo (Maltodextrin 3 grams)

Primary outcome measure

To determine the effect of Bi2muno (Bi2GOS) 1 dose of 3 g/day on the bifidobacterial components (numbers and species diversity of the specific bacterial group) of formula-fed infants' faecal microbiota

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2006

Completion date

01/04/2006

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Signed consent form
2. Age at inclusion: 8-10 weeks
3. Fully formula fed infants

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

A total of 30 healthy formula-fed infants

Key exclusion criteria

1. Breast-fed infants
2. Infants with congenital abnormalities, or with proven suspected cow's milk allergy
3. Infants of multiple gestations
4. Infants who have received antibiotics less than two weeks before the start of the study
5. Infants fed any formula containing pro- or prebiotics
6. Infants with a history of gastrointestinal dysfunction (e.g. >5 bouts of diarrhoea)

Date of first enrolment

01/02/2006

Date of final enrolment

01/04/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

School of Food Biosciences

Reading

United Kingdom

RG6 6AP

Sponsor information

Organisation

Clasado Ltd (UK)

Sponsor details

11 Warren Yard
Wolverton Mill
Milton Keynes
United Kingdom
MK12 5NW

Sponsor type

Industry

Website

<http://www.clasado.com>

ROR

<https://ror.org/04e5xac72>

Funder(s)

Funder type

Industry

Funder Name

Clasado Ltd (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration