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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/01/2006	**Overall study status** Stopped	
Last Edited 19/02/2014	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 <I>in situ</I> 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
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Wolverton Mill
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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