ISRCTN13340073 https://doi.org/10.1186/ISRCTN13340073

Probiotics for infant colic

Submission date	Recruitment status	[ ] Prospectively registered
18/08/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/08/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/08/2017	Neonatal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Colic is excessive, frequent crying in a baby who appears to be otherwise healthy. Caring for a baby with colic can be very difficult for parents. There are some over-the-counter treatments available, but there is no evidence for the effectiveness of these treatments. A recent study reported that probiotics noticeably reduced crying time. The aim of this study is to assess the effectiveness of a probiotic dietary supplement on infant colic.

Who can participate?
Infants aged less than 3 months with colic

What does the study involve?
Participating infants are randomly allocated to take either the probiotic oildrop or a placebo (dummy) oildrop once daily for a 3-week period. Their parents record crying/fussiness and stool frequency and consistency daily in a diary.

What are the possible benefits and risks of participating?
An anticipated benefit of participation in this study may be less fussing or crying.

Where is the study run from?
Chengdu New Century Women's and Children's Hospital (China)

When is the study starting and how long is it expected to run for?
November 2015 to December 2017

Who is funding the study?
Chr. Hansen A/S (Denmark)

Who is the main contact?
Cathrine Morberg

Contact information

Type(s)
Scientific

Contact name
Mrs Cathrine Morberg

Contact details
10-12 Boege Alle
Hoersholm
Denmark
2970

Additional identifiers

Protocol serial number
INV-IN941

Study information

Scientific Title
The efficacy of 3 weeks supplementation with a probiotic dietary supplement on infant colic: a randomized, double-blind, placebo-controlled, parallel group study

Study objectives
To determine the efficacy of a probiotic dietary supplement on infant colic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Ethics Committee of the Chengdu New Century Women’s and Children's Hospital, 08/01/2016, ref: ID INV-IN-941

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled parallel-group study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infant colic

Interventions
Prior to the start of the study, the allocation of subject numbers to study groups will be performed by randomization. Randomization will be stratified by infant age (≤6 weeks versus >6 weeks). The randomization lists for each stratum will be drawn up for N =200 subjects using SAS program. Randomization number will be allocated sequentially in the order in which the child enter the study. Access to the randomization list is limited to the staff that generated the random list, to the staff at Chr. Hansen who will label the products according to the

randomization list. Electronic files of the randomization list are password-protected. Hardcopies of the randomization list are protected in a sealed envelope.

The study includes a screening visit (Visit 1), a one week run-in period and a randomization visit (Visit 2) and a 3-week intervention phase with an end of study visit at day 28 (Visit 3).

After the parents of the infant have given written informed consent and the screening procedures to evaluate eligibility for the study has been completed, the infants will enter the one week run-in phase. At Visit 2, the diagnosis of colic will be evaluated based on information recorded in a diary. Only those with a confirmed colic diagnosis will be randomly assigned to one of the two study groups in a 1:1 ratio. During the 3-week intervention period, infants will consume the probiotic oildrop or a placebo oildrop once daily and caretakers will complete the daily diary for the efficacy assessments.

During the entire study, from screening until end of intervention, it is not allowed to give the infants any probiotic products other than the study products provided.

The caretaker of the infant will record crying/fussiness and stool frequency and consistency daily in a subject diary during the run-in and the intervention period. PedsQLTM, Family Impact Module will be measured weekly.

Details about baseline characteristics, demographics, medical history and concomitant medication will be documented in a Case Report Form (CRF) at Visit 1. From the beginning of the study and until the end of intervention period, adverse events will be assessed.

Intervention Type
Supplement

Primary outcome(s)
Percentage of infants achieving a reduction in the daily crying/fussing time after 3 weeks treatment. Measured daily in diary. Baseline will be the mean of crying and fussing time measured daily in the diary during run in (day -7 to -1).

Key secondary outcome(s)
1. Stool frequency and consistency, measured daily in diary using Amsterdam Stool Form. Baseline will be the mean frequency and consistency measured daily in the diary during run in (day -7 to -1)
2. Faecal IgA and calprotectin, measured at baseline (before intervention, day -1) and end of intervention (day 21)

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Infant colic defined as crying or fussing episodes lasting more than 3 hours per day and occurring at least 3 days per week within 7 days prior to enrollment (ROME III)
2. Exclusive breast fed infants at inclusion

3. Less than 3 months of age
4. Greater than 37 weeks gestation at birth
5. Birth weight of more than 2500 g

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Formula fed or combination breast fed/ formula fed infants
2. Failure to thrive (weight gain < 100 grams/week averaged from birth to the last recorded weight)
3. Major medical problems (e.g. ill, immunocompromised, major developmental or genetic abnormality
4. Gastrointestinal disorder
5. Taking antibiotics four weeks prior to enrollment
6. Using probiotics in the past two weeks prior to enrollment
7. Taking antibiotics during intervention

Date of first enrolment
01/05/2016

Date of final enrolment
30/10/2017

Locations

Countries of recruitment
China

Study participating centre
Chengdu New Century Women's and Children's Hospital
No. 77, Baojia Avenue, Qingyang District
Chengdu
China
-

Sponsor information

Organisation
Chr. Hansen A/S

ROR
https://ror.org/01mv6bt66

Funder(s)

Funder type
Industry

Funder Name
Chr. Hansen A/S

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available at the current stage due to a potential regulatory application.

IPD sharing plan summary
Not expected to be made available