ISRCTN95287767 https://doi.org/10.1186/ISRCTN95287767

Baby Biotics: Do probiotics help crying babies and their families?

Submission date	Recruitment status	[X] Prospectively registered
27/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2015	Pregnancy and Childbirth	

Plain English summary of protocol
http://www.rch.org.au/uploadedFiles/Main/Content/ccch/Baby_Biotics_FAQs.pdf

Study website
http://www.rch.org.au/ccch/for_researchers/Baby_Biotics/

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
Impact of Lactobacillus reuteri DSM 17938 on infant colic and parent mental health: a randomised double-blinded, placebo-controlled trial in breast and formula fed infants less than 3 months old

Study objectives
In a double-blind, placebo-controlled randomised trial, we aim to determine whether the probiotic Lactobacillus reuteri DSM 17938 benefits infants less than 3 months old with infant colic by:
1. Reducing the duration and episodes of infant crying
2. Improving infant sleep
3. Improving maternal mental health
4. Improving infant and family functioning, and
5. Improving parent quality adjusted life years (QALY) as an indication of intervention cost-effectiveness

We also aim to reveal underlying pathophysiogical mechanisms in infant colic by investigating changes in:
6. Gut microbiota, and
7. Faecal calprotectin levels

We hypothesise that, compared to the placebo (control) group, benefits to the L reuteri (intervention) group at 7, 14, 21, 28 days and 6 months post-randomisation will include:
1. Lower mean daily crying time (primary outcome) and fewer daily crying episodes
2. Longer infant sleep duration
3. Better mean scores on a standardised measure of maternal mental health (1 and 6 months)
4. Better mean scores on a standardised measure of infant and family functioning (1 and 6 months), and
5. Better mean scores on a standardised measure of parent QALY (1 and 6 months), indicating the intervention to be cost-effective

We also hypothesise that the intervention will, at 1 month post-randomisation:
6. Induce changes in gut microbiota, and
7. Reduce faecal calprotectin levels

On 10/12/2012 the overall trial end date was changed from 03/12/2012 to 01/05/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee of the Royal Children's Hospital, Melbourne – approval pending as of 17/08/2010 (ref: HREC #30111)

Study design
Single-centre randomised double-blind placebo-controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The intervention is Lactobacillus reuteri DSM 17938 at the concentration of 0.2 x 10^8 cfu in an oil suspension. It is administered orally to each infant as 5 drops per day (total dose 1 x 10^8 cfu /day), for 28 days.

The control is a placebo, which is identical to the intervention but without Lactobacillus reuteri DSM17938. It is also administered orally to each infant as 5 drops per day for 28 days.

The follow-up period is 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mean infant crying time (minutes per 24 hours), measured by the Barr diary, a validated measure of infant crying, at 28 days

Secondary outcome measures
1. Mean infant crying time (minutes per 24 hours), measured by the Barr diary, a validated measure of infant crying, at 7, 14, 21 days and at 6 months
2. Mean number of episodes of infant crying per 24 hours, measured by the Barr diary, a validated measure of infant crying, at 7, 14, 21, 28 days and at 6 months
3. Mean infant sleep duration (minutes per 24 hours), measured by the Barr diary, a validated measure of infant sleep duration, at 7, 14, 21, 28 days and at 6 months
4. Mean maternal mental health scores, measured by the Edinburgh Postnatal Depression Scale, with higher scores indicating more symptoms of depression, at 1 and 6 months
5. Mean infant and family functioning scores, measured by the PedsQL Infant and Family Impact scores, with higher scores indicating better functioning, at 1 and 6 months
6. Mean parent quality adjusted life years (QALY) scores, measured by the AQoL-4D, a 12-item

validated questionnaire to assess QALY and subsequently intervention cost-effectiveness, at 1 and 6 months
7. Infant faecal microbiota diversity, measured by 16S RNA amplification, at 1 month
8. Infant faecal calprotectin levels, measured by ELISA, at 1 month

Overall study start date
30/05/2011

Completion date
01/05/2013

Eligibility

Key inclusion criteria
Infants less than 3 months old (up to and excluding 13.0 weeks) with:
1. Infant colic, ie crying more than 3 hours/day for more than 3 days over 7 days (as defined by the modified Wessel's criteria) by caregiver's report
2. More than 36 weeks gestation at birth
3. Birth weight more than 2500 g

Participant type(s)
Patient

Age group
Child

Upper age limit
3 Months

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Infants with failure to thrive (weight gain less than 20 g/day averaged from birth to the last recorded weight)
2. Infants with major medical problems (eg. ill, immunocompromised, infants with major developmental or chromosomal abnormalities)
3. Infants or breastfeeding mothers using antibiotics or probiotics at the time of study recruitment
4. Families with insufficient English to understand informed consent or complete questionnaires

Date of first enrolment
30/05/2011

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
Australia

Study participating centre
Centre for Community Child Health
Melbourne
Australia
3052

Sponsor information

Organisation
Murdoch Childrens Research Institute (MCRI) (Australia)

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Sponsor type
Research organisation

Website
http://www.mcri.edu.au

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Research organisation

Funder Name

Murdoch Childrens Research Institute, Royal Children's Hospital Melbourne (Australia) - Centre for Community Child Health

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No