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Lactobacillus rhamnosus GG (ATCC 53103) in the treatment of infantile colic

Submission date 08/09/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2021	**Overall study status** Completed	
Last Edited 03/12/2024	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Infantile colic is one of the most common problems that occurs within the first months of life with a prevalence of up to 30%. As it is characterized by spells of irritability, fussing or crying that start and stop without obvious cause and lasts 3 or more hours a day, at least 3 days a week for at least 1 week, it may be very distressing to parents. Hence, any safe and effective treatment that ameliorates symptoms like crying time would be desirable.
The influence of probiotics on infant microbiota (gut bacteria) has attracted great interest in the field of infant nutrition after the discovery of human breast milk as a source of these compounds. Growing evidence underlines the fact that infantile colic can be mediated by the composition of the gut flora and immunity. Probiotics may be an important treatment option for managing infantile colic due to their anti-inflammatory properties.

Who can participate?
Breastfed infants aged between 2 and 10 weeks with infantile colic

What does the study involve?
Participants will be randomly allocated to receive five drops of either the probiotic Lactobacillus rhamnosus (ATCC 53103) or placebo daily for 28 days. Crying time per day is measured by parents using a structured diary for the 28 days of the study.

What are the possible benefits and risks of participating?
The possible benefit is the improvement of symptoms due to infantile colic with a reduction of crying time. No risks are known.

Where is the study run from?
Children's Hospital Regina Margherita di Torino (Italy)

When is the study starting and how long is it expected to run for?
July 2021 to February 2023

Who is funding the study?
Dicofarm (Italy)

Who is the main contact?
Dr Savino Francesco
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
0078279

Study information

Scientific Title
Assay of IL6 and TNF alfa in infantile colic treated with Lactobacillus GG

Study objectives
Probiotics may be an important treatment option for managing infantile colic due to their anti-inflammatory properties. This study aims to assess IL6 and TNF alfa with real-time PCR before and after administration of Lactobacillus GG.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/07/2021, Comiato Etico interaziendale AUO Città della salute AUO ospedale Mauriziano di Torino (Corso Bramante, 88/90 - 10126 Torino, Italy; +39 (0)11 6331633; email: not known), ref: P.I./Cod. Fisc. 10771180014, Prot. n° 0078279 Titolario A/2.4.8

Primary study design
Interventional

Study design
Interventional randomized double-blind placebo-controlled trial

Study type(s)
Treatment

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

Interventions
At enrollment, each infant underwent a medical examination by a pediatrician, and parents completed a questionnaire to obtain data concerning the type of delivery, birth weight, and gestational age. The doctor interviewed parents and asked them to report full-force crying by means of a well-validated three-day diary before the fecal sample collection. A diet eliminating cow's milk and dairy products for the breastfeeding mother was requested. The mean daily minutes of crying was calculated as a sum of crying, fussing, and unsuitable crying using a parental diary.

Participants are randomized to take five drops of Lactobacillus rhamnosus (ATCC 53103) (5 × 10e9 colony for units per day) or placebo for a 28-day study period.

Randomization was done using a random-digit method, on the basis of computer-generated numbers. The researchers used a two treatments randomization scheme with a random block of varying size (Stata Statistical Software: Release 9. StataCorp LP, College Station, TX, USA. Ralloc Procedure).

The probiotic study product consisted of a suspension of freeze-dried L. rhamnousus ATCC53103 in a mixture of maize oil and mono and diglyceride oil supplied in a 5 ml dark bottle fitted with a dropper cap. The placebo was an identical mixture of maize oil and mono and diglyceride oil in appearance and taste but without the probiotic. Both formulations were administered during the morning in five drops, once a day, 30 min before the feed, for a period of 28 days.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lactobacillus rhamnosus (ATCC 53103)

Primary outcome(s)
Crying time per day measured by parents using a structured diary for the 28 days of the study period

Key secondary outcome(s)
Interleukin 6 and tumor necrosis factor alfa evaluated with real-time PCR at day 0 and day 28

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Infants aged between 2 and 10 weeks
2. Gestational age between 37 and 40 weeks
3. Birth weight between 2700 and 4200 g
4. Exclusively breastfed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Weeks

Upper age limit
10 Weeks

Sex
All

Key exclusion criteria
1. Clinical evidence of chronic illness or gastrointestinal disorders
2. Received antibiotics or probiotics in the week preceding recruitment

Date of first enrolment
23/07/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Italy

Study participating centre
Ospedale Infantile Regina Margherita
piazza Polonia, 94
Torino
Italy
10126

Sponsor information

Organisation
Dicofarm

Funder(s)

Funder type
Industry

Funder Name
Dicofarm

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Abstract: N-PW018	14/05/2024	03/12/2024	No	No
Participant information sheet			09/09/2021	No	Yes
Protocol file			09/09/2021	No	No