

The efficacy of probiotics for prevention of necrotising enterocolitis in very low birth weight infants: a randomised clinical trial

Submission date 09/08/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 17/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/02/2011	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Taciana Duque-Braga

Contact details

IMIP - UTI Neonatal
Rua dos Coelhos, 300
Recife
Brazil
50070-550

Additional identifiers

Study information

Scientific Title

Study objectives

Necrotising enterocolitis is an inflammatory bowel disease. It is the most common gastrointestinal emergency in neonates mainly associated with prematurity and inappropriate gastrointestinal colonisation by bacteria.

The study hypothesis is that the use of probiotics - Lactobacillus casei and Bifidobacterium breve - will have a positive impact on very low birth weight infants related to:

1. The reduction of the risk of necrotising enterocolitis
2. The reduction of the time span to reach the full enteral intake
3. The reduction of pathogenic bacteria in the faeces culture

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee in Research of the Institute for Maternal/Infant Health (Instituto Materno Infantil de Pernambuco [IMIP]) (Brazil) (c/o Prof Fernando Figueira) approved in August 2006.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Necrotising enterocolitis in very low birth weight infants.

Interventions

The participants will be randomised into two groups of 315 infants:

Control group: 3 ml of pasteurised human milk once a day on the second to the 30th day of life, or at the discharge if it happens before the 30th day.

Intervention group: Lactobacillus casei and Bifidobacterium breve (Yakult - LB) diluted with 3 ml of pasteurised human milk once a day on the second to the 30th day of life, or at the discharge if it happens before the 30th day.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Probiotics (Lactobacillus casei and Bifidobacterium breve)

Primary outcome(s)

To compare the frequency of the necrotising enterocolitis classified as higher or equal to 2 according to Bells criteria modified by Walsh and Kleigman during the first 30 days of life.

Key secondary outcome(s)

1. To compare the frequency of pathogenic bacteria in the faeces tested weekly during the first month of life, in neonates treated with or without antibiotics; collecting stool samples (rectal swab) on 1, 7, 14 and 30 days of life, under sterile conditions and immediately transported to the bacteriology laboratory situated in the same building for processing
2. To compare the duration of birth weight recovery; assessment of the weight of the infants daily during the hospital stay
3. To compare the time taken to reach full enteral feeds - defined as a daily intake of 120 ml/Kg; across the diary registration of the enteral feeds volumes during the hospital stay
4. To compare the duration of hospital stay; the time between the admission and the discharge

Completion date

01/05/2009

Eligibility

Key inclusion criteria

Infants with birth weight from 750 g to 1500 g admitted in the Neonatal intensive Care Unit of the Institute for Maternal/Infant Health (Instituto Materno Infantil de Pernambuco [IMIP]).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

Key exclusion criteria

1. Newborns with severe congenital malformations
2. Newborns with severe chromosomal abnormalities

Date of first enrolment

01/09/2007

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Brazil

Study participating centre

IMIP - UTI Neonatal

Recife

Brazil

50070-550

Sponsor information

Organisation

Institute for Maternal/Infant Health (Instituto Materno Infantil de Pernambuco [IMIP]) (Brazil)

ROR

<https://ror.org/01rtyyz33>

Funder(s)

Funder type

Government

Funder Name

Laboratorio Yakult (www.yakultfarma.com.br) (Brazil) - providing the probiotics treatments

Funder Name

Institute for Maternal/Infant Health (Instituto Materno Infantil [IMIP]) (Brazil) - c/o Prof Fernando Figueira, where study and assessments will be carried out

Funder Name

The National Council of Scientific and Technologic Development (CNPq) (Brazil) - granted financial support to the research project

Results and Publications

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	01/01/2011		Yes	No