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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/08/2007	**Overall study status** Completed	
Last Edited 02/02/2011	**Condition category** Digestive System	

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
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/09/2007

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

Age group
Neonate

Sex
Not Specified

Target number of participants
630

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)

Sponsor details
Rua dos Coelhos
300 - Boa Vista
Recife
Brazil
50070-550

Sponsor type
Hospital/treatment centre

Website
http://www.imip.org.br/

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

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	01/01/2011		Yes	No