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Effect of oral probiotic supplementation on the rate of hospital acquired infection and necrotizing enterocolitis in preterm very low birth weight infants

Submission date
18/04/2011

Recruitment status
No longer recruiting

Registration date
28/04/2011

Overall study status
Completed

Last Edited
28/04/2011

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
Nosocomial infections and necrotizing enterocolitis in preterm very low birth weight neonates treated with lactobacillus acidophilus and bifidobacterium infantis in an intensive care unit : a randomized controlled study

Study objectives
Daily enteral probiotics supplementation can reduce nosocomial infections and necrotizing enterocolitis (NEC) among very low birth weight (VLBW) infants in a neonatal intensive care unit

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Institutional Review Board of the Faculty of Medicine, Chilalongkorn University approved on 28th February 2003, Ref: 065/2003

Study design
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Hospital acquired infection and necrotizing enterocolitis in neonates

Interventions
Daily enteral probiotic supplementation of live Lactobacillus acidophilus and Bifidobacterium infantis at a dose of 2.5 x 108 CFU of each strain once a day for at least 28 days versus placebo

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Nosocomial Infections

Secondary outcome measures
1. Necrotizing enterocolitis (NEC)
2. Feeding tolerance
3. Time to reach full enteral feeding

Overall study start date
01/01/2005

Completion date
31/03/2008

Eligibility

Key inclusion criteria
1. VLBW preterm infants (gestational age (GA) < 35 weeks , body weight (BW) < 1.5 kg)
2. Admitted to the neonatal intensive care unit (NICU) who survived the first 3 days of life

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Infants with chromosome abnormality
2. Infants with severe congenital defects
3. Infants with gastrointestinal anomalies (e.g. omphalocele, gastroschisis, intestinal obstruction)
4. Infants with unstable hemodynamic status

Date of first enrolment
01/01/2005

Date of final enrolment
31/03/2008

Locations

Countries of recruitment

Thailand

Study participating centre
Department of Pediatrics
Bangkok
Thailand
10330

Sponsor information

Organisation
Faculty of Medicine Chulalongkorn University (Thailand)

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Sponsor type
University/education

ROR
https://ror.org/028wp3y58

Funder(s)

Funder type
University/education

Funder Name
Faculty of Medicine Chulalongkorn University (Thailand)

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