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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

Protocol serial number
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

Study type(s)
Prevention

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(s)
Nosocomial Infections

Key secondary outcome(s))
1. Necrotizing enterocolitis (NEC)
2. Feeding tolerance
3. Time to reach full enteral feeding

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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)

ROR

https://ror.org/028wp3y58

Funder(s)

Funder type
University/education

Funder Name
Faculty of Medicine Chulalongkorn University (Thailand)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration