

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	<input type="checkbox"/> Prospectively registered
Registration date 28/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/04/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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, Chulalongkorn 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 2.5×10^8 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