

Lactobacillus casei strain GG in the treatment of infants with acute watery diarrhoea: a randomised, double-blind, placebo controlled clinical trial

Submission date 30/08/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/08/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/08/2007	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Eduardo Salazar-Lindo

Contact details

Av. El Polo 740 Of. C-410

Lima

Peru

033

+51 1 435 7800

edsalaza@ec-red.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute watery diarrhoea

Interventions

1. Oral rehydration
2. Feeding with age-appropriate infant's food
3. Randomised to receive a milk formula with or without Lactobacillus casei strain GG

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1991

Completion date

01/06/1992

Eligibility

Key inclusion criteria

Male infants aged 3 - 36 months brought for treatment of acute watery diarrhoea with mild-moderate dehydration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

179

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/1991

Date of final enrolment

01/06/1992

Locations

Countries of recruitment

Peru

Study participating centre

Av. El Polo 740 Of. C-410

Lima

Peru

033

Sponsor information

Organisation

Universidad Peruana Cayetano Heredia (Peru)

Sponsor details

Av. Honorio Delgado 430

Lima

Peru

031

postmaster@upch.edu.pe

Sponsor type

University/education

ROR

<https://ror.org/03yczjf25>

Funder(s)

Funder type

Industry

Funder Name

The study was supported by a grant from Valio Ltd, Helsinki (Finland) to the Child Health Foundation, Columbia, Maryland (USA)

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	02/09/2004		Yes	No

