

Effect of probiotics in acute childhood diarrhea

Submission date 25/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/01/2019	Condition category Digestive System	<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 Chien-Chang Chen

Contact details

5, Fu-Hsing Street
Kwei-Shan
Taoyuan
Taiwan
333

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00463190

Secondary identifying numbers

N/A

Study information

Scientific Title

Effect of probiotics (Bio-Three®) in children's enterocolitis

Study objectives

Probiotics have been shown to be effective in the treatment of these conditions. There are many mechanisms by which probiotics enhance intestinal health, including stimulation of immunity, competition for limited nutrients, inhibition of epithelial and mucosal adherence, inhibition of epithelial invasion and production of antimicrobial substances.

Hypothesis:

Probiotics medication (Bio-Three®) could inhibit gastrointestinal infection and reduce its inflammatory response in the intestine. We plan to explore the bacterial count (microbiology) and subsequent immune response in probiotic inhibition of enterocolitis in children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Chang Gung Memorial Hospital, Taoyuan, Taiwan. Date of approval: 10/01/2006

Study design

Randomised, double-blind (subject, caregiver, investigator), placebo-controlled, parallel-assignment, safety/efficacy, single-centre study

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

Enterocolitis

Interventions

Treatment group: Oral probiotics (Bio-Three®) 3 times daily for 7 days

Control group: Placebo 3 times daily for 7 days

Bio-three® contains a mixture of *Bacillus mesentericus*, *Streptococcus faecalis* and *Clostridium butyricum*. Total bacterial count: 1.5×10^8 colony forming units (cfu) per tablet.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

To determine whether probiotics medication Bio-Three® inhibits gastrointestinal infection and reduce its inflammatory response in the intestine. The following were assessed:

1. Clinical symptoms 2 days after medication
2. Microbiology study 3 days and one week after medication

The time and the consistency of every stool were recorded and the total hospital duration was calculated.

Severity of diarrhoea was evaluated according to the following parameters: number of stools, fecal consistency, the presence or absence of mucus, and blood in stools.

Secondary outcome measures

Other clinical symptoms/signs including fever, vomiting, dehydration, abdominal pain, bloating, daily dietary intake and appetite were also recorded for 7 to 10 days.

Overall study start date

01/02/2006

Completion date

30/11/2007

Eligibility**Key inclusion criteria**

1. Age: From 3 months to 12 years, both male and female children
2. Clinical symptom of diarrhoea less than 3 days

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Months

Upper age limit

12 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Severe abdominal distension with risk of bowel perforation
2. Risk of sepsis
3. Past history of surgical operation of gastrointestinal tracts

Date of first enrolment

01/02/2006

Date of final enrolment

30/11/2007

Locations

Countries of recruitment

Taiwan

Study participating centre

5, Fu-Hsing Street

Taoyuan

Taiwan

333

Sponsor information

Organisation

Maywufa Company Ltd (Taiwan)

Sponsor details

5F, 167, Fu-Hsing North Road

Taipei

Taiwan

105

Sponsor type

Industry

ROR

<https://ror.org/01m15jk16>

Funder(s)

Funder type

Industry

Funder Name

Chang Gung Memorial Hospital (Taiwan)

Funder Name

Maywufa Company Ltd (Taiwan)

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	01/02/2010	31/01/2019	Yes	No