ISRCTN30646529 https://doi.org/10.1186/ISRCTN30646529

# Effect of probiotics in acute childhood diarrhea

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|---|---|---|
| **Submission date**<br>25/04/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>01/05/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>31/01/2019 | **Condition category**<br>Digestive System | |

**Plain English Summary**
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**
NCT00463190

**Secondary identifying numbers**
N/A

## Study information

**Scientific Title**

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

## Study hypothesis
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

## Condition
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 butyricium. Total bacterial count: 1.5 x 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

### Overall study end date
30/11/2007

## Eligibility

### Participant 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

### Participant exclusion criteria

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

### Recruitment start date
01/02/2006

### Recruitment end date
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 |