

# Effect of probiotics in acute childhood diarrhea

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00463190

### Protocol serial number

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

#### **Study type(s)**

Treatment

#### **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:  $1.5 \times 10^8$  colony forming units (cfu) per tablet.

#### **Intervention Type**

Other

#### **Phase**

Not Specified

#### **Primary outcome(s)**

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.

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

3 months

### **Upper age limit**

12 years

### **Sex**

All

### **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  
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## Sponsor information

**Organisation**  
Maywufa Company Ltd (Taiwan)

**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

### 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?
<a href="#">Results article</a>	results	01/02/2010	31/01/2019	Yes	No