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Effect of probiotics in acute childhood diarrhea

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

Plain English summary of protocol
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 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 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

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
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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