

Probiotics for treatment of acute childhood diarrhea

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| Submission date 08/02/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/02/2018 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 04/08/2020 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The aim of this study is to assess the effectiveness and safety of a combination of three probiotics, *Bifidobacterium lactis* Bi-07, *Lactobacillus rhamnosus* HN001 and *Lactobacillus acidophilus* NCFM, added to rehydration therapy in the treatment of acute watery diarrhea in hospitalized children.

Who can participate?

Infants and children with mild to moderate acute diarrhea

What does the study involve?

Participants are randomly allocated to receive either conventional treatment for diarrhea or conventional treatment for diarrhea plus probiotics. The duration of diarrhea is measured.

What are the possible benefits and risks of participating?

The use of probiotics may shorten the duration of diarrhea and improve stool consistency. The potential risks include a minor allergy to the probiotics.

Where is the study run from?

Chengdu Women & Children's Central Hospital (China)

When is the study starting and how long is it expected to run for?

November 2016 to September 2017

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Ke Chen

Contact information

Type(s)

Scientific

Contact name

Dr Ke Chen

Contact details

No. 1617, Riyue Avenue
Qingyang District
Chengdu
China
610031

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Three combination probiotics for treatment of acute childhood diarrhea: an open labelled, randomized controlled trial

Study objectives

To assess the efficacy and safety of three combination probiotics as an adjunct to rehydration therapy in the treatment of hospitalized children because of acute watery diarrhea.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The institutional ethics committee of Anhui Provincial Hospital, 13/12/2016

Study design

Multicenter randomized open-label parallel-group controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute childhood diarrhea

Interventions

The randomized sequence was generated by a person not directly involved in execution of the study. The RAND function of Excel (Microsoft, Redmond, WA, USA) was used to generate computer randomly permuted codes. Simple randomization was used.

All included eligible diarrheal children were randomized to either:

1. Intervention group (IG): The preparation of three combination probiotics containing three unique strains of bacteria, Bifidobacterium lactis Bi-07, Lactobacillus rhamnosus HN001 and Lactobacillus acidophilus NCFM in addition to the standard management of diarrhea. The three combination probiotics was given as a single sachet containing more than 10 billion colony forming units (CFU) once a day from the beginning of the treatment for diarrhea until 7 days after the drug withdrawal
2. Control group (CG): No probiotic medication

Study children were managed according to the WHO guidelines which included oral rehydration therapy (ORT) with reduced osmolarity ORS and zinc (zinc sulphate dispersible tablets) 20 mg /day and continued feeding. Severe dehydration was managed with intravenous fluids (ringer lactate) as per WHO guidelines. For one single subject, the intervention duration is once the day from the beginning of the treatment for diarrhea until 7 days after drug withdrawal.

Intervention Type

Supplement

Primary outcome(s)

Duration of diarrhea [time in hours from enrolment to the last abnormal (loose or liquid) stool], measured using an appropriate CRF every day during the intervention

Key secondary outcome(s)

Number of loose stools per day during the entire episode, measured using an appropriate CRF every day during the intervention

Completion date

30/09/2017

Eligibility

Key inclusion criteria

Infants and children with an episode of mild to moderate acute diarrhea (>4 (semi)watery stools /day according to Bristol criteria (Bristol criteria ≥ 6)) lasting more than 12 h and less than 72 h, requiring hospitalization

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

194

Key exclusion criteria

1. Subjects with clinical features of hypovolemic shock and/or necessitating admission at the intensive care unit
2. Taking immunosuppressive therapy
3. Known immunodeficiency disorder
4. Pancreatic dysfunction
5. Bloody diarrhea
6. Chronic gastrointestinal disease
7. Short bowel syndrome
8. Bilious or bloody vomitus
9. Probiotics 1 month before admission
10. Severe malnutrition

Date of first enrolment

01/05/2017

Date of final enrolment

25/09/2017

Locations

Countries of recruitment

China

Study participating centre

Chengdu Women & Children's Central Hospital

No. 1617

Riyue Avenue

Qingyang District

Chengdu

China

610031

Sponsor information

Organisation

Infinitus (China) Company Ltd

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ke Chen.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 12/08/2020 | 04/08/2020 | Yes | No |