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Probiotics for treatment of acute childhood diarrhea

Submission date	Recruitment status	[_] Prospectively registered
08/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/02/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/08/2020	Signs and Symptoms	

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
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Chengdu
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610031

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 permutated 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 measure
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

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

Overall study start date
01/11/2016

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

Age group
Child

Sex
Both

Target number of participants
216

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

Sponsor details
No.12, Jiangxi Road
Zhujiang New City
Tianhe District
Guangzhou
China
510091

Sponsor type
Industry

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and presentations at professional conferences.

Intention to publish date
30/09/2018

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