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Probiotics for the treatment of acute gastroenteritis: a randomised clinical trial with five different preparations

Submission date 01/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/04/2007	**Overall study status** Completed	
Last Edited 06/10/2020	**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

Secondary identifying numbers
00081877

Study information

Scientific Title
Probiotics for the treatment of acute gastroenteritis: a randomised clinical trial with five different preparations

Acronym
Probiotics in acute gastroenteritis

Study objectives
Probiotics are increasingly used adjunctive to oral rehydration solution to treat childhood gastroenteritis. Numerous preparations are available, but clinical efficacy has not been proven for many of them. We aimed to comparatively investigate the efficacy of five probiotic preparations in the treatment of acute gastroenteritis in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol and consent form were approved by the Ethics Committee of the School of Medicine at the University of Naples Federico II on the 1st September 1999 (ref: 5407).

Study design
Multicentre, single-blind, controlled trial

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
Acute gastroenteritis

Interventions
All enrolled children were rehydrated orally with 60 mMol Na+ Oral Rehydration Solution (ORS) for 36 hours and then re-fed with full strength, lactose-containing formula or cow's milk, depending on age. In addition to the above supportive treatment, children were randomized to the following groups:
1. Oral rehydration solution alone (control group) containing Na+ 60 mEq/L, K+ 20 mEq/L, Glucose 16.7 g/L
2. Lactobacillus casei strain rhamnosus GG (Lactobacillus GG; 6 x 10^9 CFU/dose, bid)
3. Saccharomyces boulardii (5 x 10^9 live micro-organisms/dose, bid)
4. Bacillus clausii (10^9 CFU/dose, bid)
5. Mix of Lactobacillus delbrueckii var. bulgaricus + Streptococcus thermophilus + Lactobacillus

acidophilus + Bifidobacterium bifidum (10^9 CFU + 10^9 CFU + 10^9 CFU + 5 x 10^8 CFU/dose, bid)
6. Enterococcus faecium strain SF68 (7.5 x 10^7 CFU/dose, bid).

Probiotic preparations were prescribed for 5 days and administered by the oral route suspended in 20 ml of water according to the manufacturers' indications.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oral Rehydration Solution

Primary outcome measure
Diarrhoea duration defined as the time in hours from the first to the last abnormal (loose or liquid) stools preceding a normal stool output.

Secondary outcome measures
1. Duration of vomiting and fever, defined by the time in days from the first to the last episode of vomiting and/or fever (boby temperature > 37.5°C)
2. Hospitalization investigated as hospital admissions rate

Overall study start date
01/10/1999

Completion date
30/09/2000

Eligibility

Key inclusion criteria
Children three to 36 months of age seen in paediatricians' offices because of diarrhoea were eligible for the study. Patients presenting diarrhoea lasting less than 48 hours with informed consent given from parents were included in the study.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
540

Key exclusion criteria
1. Malnutrition as judged by body weight/height ratio
2. Clinical signs of severe dehydration
3. Clinical signs of a coexisting acute systemic illness (meningitis, sepsis, pneumonia)
4. Immunodeficiency
5. Underlying severe chronic diseases
6. Cystic fibrosis
7. Food allergy or other chronic gastrointestinal diseases
8. Use of probiotics in the previous 3 weeks
9. Use of antibiotics or any antidiarrhoeal medication in the previous 3 weeks and during study medication
10. Poor compliance (defined by administration of less than four doses of study medication)

Date of first enrolment
01/10/1999

Date of final enrolment
30/09/2000

Locations

Countries of recruitment
Italy

Study participating centre
via Pansini 5
Naples
Italy
80131

Sponsor information

Organisation
Department of Pediatrics, University of Naples Federico II (Italy)

Sponsor details
via Pansini 5
Naples
Italy
80131

Sponsor type
University/education

ROR

https://ror.org/05290cv24

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The research was sponsored by the Department of Pediatrics of the University of Naples Federico II (Italy)

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	18/08/2007		Yes	No