

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>01/03/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>27/04/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>06/10/2020       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Alfredo Guarino

### Contact details

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Naples  
Italy  
80131

## Additional identifiers

### Protocol serial number

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).

### Primary study design

Interventional

### Study design

Multicentre, single-blind, controlled trial

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Acute gastroenteritis

### Interventions

All enrolled children were rehydrated orally with 60 mMol Na<sup>+</sup> 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<sup>+</sup> 60 mEq/L, K<sup>+</sup> 20 mEq/L, Glucose 16.7 g/L
2. Lactobacillus casei strain rhamnosus GG (Lactobacillus GG;  $6 \times 10^9$  CFU/dose, bid)
3. Saccharomyces boulardii ( $5 \times 10^9$  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 +  $5 \times 10^8$  CFU/dose, bid)
6. Enterococcus faecium strain SF68 ( $7.5 \times 10^7$  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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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)

**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

**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 | 18/08/2007   |            | Yes            | No              |