

# Saccharomyces boulardii for the PREvention of Antibiotic-associated and Clostridium difficile-associated Diarrhoea in adult hospitalised patients

**Submission date**

04/03/2011

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

17/03/2011

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

08/08/2013

**Condition category**

Infections and Infestations

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

2008-001426-14

**Protocol serial number**

EudraCT 2008-001426-14

# Study information

## Scientific Title

Saccharomyces boulardii for the prevention of antibiotic-associated and Clostridium difficile-associated diarrhoea in adult hospitalised patients: a single-centre, randomised, double-blind, placebo-controlled trial

## Acronym

PREDA

## Study objectives

To test the effect of Saccharomyces boulardii on the occurrence of antibiotic-associated diarrhoea and Clostridium difficile-associated diarrhoea in hospitalised patients receiving antibiotics.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of A. Manzoni Hospital, AO Provincia di Lecco approved on 2 April 2008

## Study design

Single-centre randomised double-blind placebo-controlled parallel-group trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Antibiotic-associated-diarrhoea, Clostridium difficile-associated diarrhoea

## Interventions

Probiotic capsule, consisting of a lyophilised preparation containing  $5 \times 10^9$  colony forming units of *S. boulardii*, twice daily, in fasting conditions, starting within 48 hours after the beginning of antibiotic therapy and continuing until 7 days after its discontinuation.

The control group will be given placebo capsules, prepared by the hospital pharmacy, containing rice flour and with identical appearance, taste and smell as the probiotic capsules, according to the same time schedule.

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Saccharomyces boulardii

**Primary outcome(s)**

1. Antibiotic-associated diarrhoea, defined as the presence of more than three passages of liquid stools per day for at least 2 days or at least five in less than 48 hours
2. Clostridium difficile-associated diarrhoea, defined as antibiotic-associated diarrhoea with positive testing for Clostridium difficile toxins A and/or B

**Key secondary outcome(s)**

1. Mortality
2. Adverse effects

**Completion date**

31/07/2010

**Eligibility****Key inclusion criteria**

Eligible patients were those aged over 50 before to be given antibiotics or on antibiotic regimen for less than 48 hours, regardless of the number of antibiotic medications and route of administration, for the treatment of a proven or suspected infection or for prophylaxis.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Diarrhoea accounting for hospital admission or on-going at the time of starting antibiotics
2. Regular intake of probiotics (assumed as specific products, thus excluding those mixed in dairy or other foods) in the period preceding the hospital admission
3. Inability or unwilling to give written informed consent
4. Inability to assume tablets orally or through naso-enteric tubes
5. On-going severe acute pancreatitis

**Date of first enrolment**

02/04/2009

**Date of final enrolment**

31/07/2010

**Locations****Countries of recruitment**

Italy

### Study participating centre

Via dell'Eremo 9/11

Lecco

Italy

23900

## Sponsor information

### Organisation

A. Manzoni Hospital, AO Provincia di Lecco (Italy)

### ROR

<https://ror.org/030kaa114>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

A. Manzoni Hospital, AO Provincia di Lecco (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	01/06/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes