

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 | <input type="checkbox"/> Prospectively registered |
| Registration date 17/03/2011 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 08/08/2013 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Pietro Pozzoni

Contact details

Via dell'Eremo 9/11

Lecco

Italy

23900

+39 (0)34 148 9670

p.pozzoni@ospedale.lecco.it

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 5×10^9 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/06/2012 | | Yes | No |