

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

Contact name

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Additional identifiers

EudraCT/CTIS number

2008-001426-14

IRAS number**ClinicalTrials.gov number**

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, the contact details to request a patient information sheet is: Agostino Colli Department of Medicine, A. Manzoni Hospital, Via dell'Eremo 9/11, 23900 Lecco, Italy phone : +39(0)34 148 9670 fax +39(0)34 148 9671 email: a.colli@ospedale.lecco.it

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 measure

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

Secondary outcome measures

1. Mortality
2. Adverse effects

Overall study start date

02/04/2009

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

Age group

Adult

Sex

Both

Target number of participants

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)

Sponsor details

Via dell'Eremo 9/11

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23900

+39 (0)34 148 9670

a.colli@ospedale.lecco.it

Sponsor type

Hospital/treatment centre

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

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	01/06/2012		Yes	No