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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

Registration date
17/03/2011

Overall study status
Completed

Last Edited
08/08/2013

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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 x 109 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