ISRCTN46764354 https://doi.org/10.1186/ISRCTN46764354

Effects of PRObiotic yoghourt on the prevention of antibiotic-associated DIArrhoea (AAD)

Submission date
12/09/2013

Recruitment status
No longer recruiting

Registration date
18/09/2013

Overall study status
Completed

Last Edited
02/10/2013

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Antibiotic treatment is associated with changes in the micro-organisms present in the intestine that are sometimes associated with diarrhoea (AAD). Some studies suggest that the oral intake of non-infective micro-organisms (probiotics) may reduce the risk of AAD. This study aims to find out the effect of a probiotic-enriched yoghourt as compared to a standard yoghourt on the incidence of AAD in patients admitted to the hospital that start antibiotic therapy.

Who can participate?
Adults admitted to the participating hospital and who are prescribed antibiotic therapy are eligible to participate in the study.

What does the study involve?
Patients will be randomly assigned to receive either standard yoghourt (placebo group) or probiotic yoghourt (intervention/probiotic group) or no yoghourt at all. Medical care will be identical whether they agree to participate or not and for all patients included in the study. Both yoghourts will be packed in identical containers and neither the participants nor the investigators will know whether the yoghourt contains probiotics until the end of the study. If they are included in one of the yoghourt groups, they will be asked to consume 150-200 ml of the study yoghourt up to one week after the end of the antibiotic treatment. They will be asked to report whether they develop diarrhoea (more than two soft stools per day) up to one month after participating in the study.

What are the possible benefits and risks of participating?
Participants may potentially benefit from a reduction in the occurrence of diarrhoea. The inconveniences of participating are related to the consuming of the yoghourts. The micro-organisms included in both yoghourts are present in a variety of commercial yoghourts and are considered to be safe. However, basic lab tests as well as daily clinical assessment will be conducted during their hospital stay.

Where is the study run from?
The study is run in the medical wards of Hospital Universitario Fundación Alcorcon (a University Urban Hospital), in Alcorcón, Madrid, Spain.

When is the study starting and how long is it expected to run for?
The study started in May 2005 and ended in January 2008.

Who is funding the study?
The study is funded by the Spanish Ministry of Science (Spain).

Who is the main contact?
Dr Maria Velasco
mvelasco@fhalcorcon.es

Contact information

Type(s)
Scientific

Contact name
Dr Maria Velasco

Contact details
Hospital Universitario Fundación Alcorcon
Budapest 1
Alcorcon
Spain
28922
mvelasco@fhalcorcon.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AGL2004-07285-C02-02

Study information

Scientific Title
Probiotic yoghourt for the prevention of antibiotic-associated diarrhoea in adults: a randomized double blind placebo-controlled trial

Acronym
PRODIA

Study objectives
Probiotic bacteria may be useful in prevention of antibiotic-associated diarrhoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of Hospital Universitario Fundación Alcorcón approved the final protocol (February 2004)

Study design
Single center randomized double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Antibiotic-associated diarrhoea

Interventions
Patients were randomized (2:2:1) to receive 200 ml of:
1. placebo yoghourt (S. thermophilus 10^9 ufc/ml, L bulgaricus 10^7 ufc/ml), (placebo group)
2. probiotic yoghourt (previous plus L. acidophilus 10^7 ufc/ml, B. lactis 10^8 ufc/ml, L. casei 10^7 ufc/ml) (intervention / probiotic group)
3. no yoghourt (unblinded control group)
daily from the beginning of the antibiotic therapy for up to 5 days after stopping the antibiotic treatment. They were followed up for one month.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The rate of diarrhoea up to one month after the end of antibiotic therapy. WHO definition of diarrhoea was used: 3 or more loose or watery stools per day for two or more days.

Secondary outcome measures
1. Severity of diarrhoea defined as the maximum number of stools per day; length of diarrhoea (days with more than two loose stools)
2. Necessity to stop antibiotic treatment to treat AAD
3. Necessity to use endovenous fluid to treat AAD
4. Prolonged hospital admission or readmission because of AAD
5. Mortality
6. Tolerance to yoghourt and compliance

All outcomes were evaluated, followed-up for one month.

Overall study start date
01/05/2005

Completion date
31/01/2008

Eligibility

Key inclusion criteria
1. Adults patients, both male and non-pregnant female, older than 18 years who are prescribed amoxycilline-clavulanate or levofloxacin (oral or intravenous) in their treatments and are able to eat and drink
2. Patients or relatives must be able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Pregnancy
2. Allergy to penicillins or levofloxacin
3. Known lactose intolerance or intolerance to dairy products
4. Diarrhoea on admission or within the preceding week
5. Reported recurrent diarrhoea or bowel disease that could result in diarrhoea
6. Severe immunosuppression
7. Active neoplasia

8. HIV infection
9. Regular probiotic treatment before admission, or laxative use or enema in the 48 hours before admission

Date of first enrolment
01/05/2005

Date of final enrolment
31/01/2008

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Fundación Alcorcon
Alcorcon
Spain
28922

Sponsor information

Organisation
University Hospital Foundation Alcorcón (Hospital Universitario Fundación Alcorcón) (Spain)

Sponsor details
Unidad de Investigacion / Research Unit
Budapest 1
Alcorcon
Madrid
Spain
28922
+34 91 621 94 00
unidadinvestigacion@fhalcorcon.es

Sponsor type
Hospital/treatment centre

Website
http://www.madrid.org/hospitalfundacionalcorcon

ROR
https://ror.org/01435q086

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Science (Spain)

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