

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

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<b>Registration date</b> 18/09/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/10/2013	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Maria Velasco

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

AGL2004-07285-C02-02

## Study information

### Scientific Title

Probiotic yoghurt 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 yoghurt (*S. thermophilus*  $10^9$  ufc/ml, *L. bulgaricus*  $10^7$  ufc/ml), (placebo group)
2. probiotic yoghurt (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 yoghurt (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**

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**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