# A study to investigate the effect of probiotics on faecal flora - does administration of the probiotic 'Acidophilus' reduce counts of Enterobacteriaceae in the intestines of healthy volunteers?

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/09/2004	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	Results
<b>Last Edited</b> 28/11/2014	Condition category Infections and Infestations	Individual participant data
		Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr J S Soothill

#### Contact details

Microbiology Great Ormond Street Hospital Great Ormond Street London United Kingdom WC1N 3JH

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

#### Secondary identifying numbers

N0012128241

# Study information

#### Scientific Title

A study to investigate the effect of probiotics on faecal flora - does administration of the probiotic 'Acidophilus' reduce counts of Enterobacteriaceae in the intestines of healthy volunteers?

#### **Study objectives**

To investigate whether administration of a probiotic preparation reduces the carriage of Enterobacteriaceae in the gut.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

#### Study type(s)

Other

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Infections and Infestations: Gram-negative bacteriae

#### **Interventions**

- 1. Probiotics treatment for gut infection
- 2. No treatment

#### Intervention Type

Other

#### Primary outcome measure

Not provided at time of registration

#### Secondary outcome measures

Not provided at time of registration

## Overall study start date

01/03/2002

## Completion date

30/11/2005

# **Eligibility**

## Key inclusion criteria

Healthy adult volunteers

#### Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

## Target number of participants

Not provided at time of registration

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/03/2002

#### Date of final enrolment

30/11/2005

## Locations

## Countries of recruitment

England

**United Kingdom** 

## Study participating centre Great Ormond Street Hospital

London United Kingdom WC1N 3JH

# Sponsor information

#### Organisation

Department of Health

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Great Ormond Street Hospital for Children

## Alternative Name(s)

**GOSH** 

## **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Local government

#### Location

**United Kingdom** 

#### **Funder Name**

Institute of Child Health, University College London

## Alternative Name(s)

## UCL Great Ormond Street Institute of Child Health, GOS ICH

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Universities (academic only)

#### Location

**United Kingdom** 

## **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