# Effect of stopping proton pump inhibitors (PPI) on the incidence of Clostridium difficile diarrhoea (CDD)

Submission date Recruitment status Prospectively registered 30/09/2004 No longer recruiting [ ] Protocol Statistical analysis plan Registration date Overall study status 30/09/2004 Completed [ ] Results Individual participant data Last Edited Condition category Record updated in last year Digestive System 17/04/2015

Plain English summary of protocol

Not provided at time of registration

#### Contact information

Type(s)

Scientific

#### Contact name

Dr R Cunningham

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0185139377

# Study information

#### Scientific Title

Effect of stopping proton pump inhibitors (PPI) on the incidence of Clostridium difficile diarrhoea (CDD)

#### Study objectives

To determine whether restricting unnecessary use of PPIs reduces the incidence of Clostridium difficile diarrhoea in hospital inpatients

#### 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)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

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

Digestive System: Diarrhoea

#### **Interventions**

Randomised controlled intervention study to determine whether restriction of PPI use to National Institute for Clinical Excellence (NICE) approved indications has an effect on subsequent incidence of Clostridium difficile diarrhoea (CDD). Interventions compared are stopping PPIs versus non stopping PPIs.

#### **Intervention Type**

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

#### Incidence of CDD

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

11/03/2004

#### Completion date

28/09/2005

# **Eligibility**

#### Key inclusion criteria

400 patients aged 65 or over admitted to hospital via Medical Assessment Unit (MAU) who are taking PPIs.

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

400

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

11/03/2004

#### Date of final enrolment

28/09/2005

### Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre Derriford Hospital

Plymouth

# 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

Plymouth Hospitals NHS Trust (UK)

## **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