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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R Cunningham

Contact details
Microbiology Dept.
Level 05
Derriford Hospital
Derriford
Plymouth
United Kingdom
PL6 8DH

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

United Kingdom
PL6 8DH

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