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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
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/04/2015	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Incidence of CDD

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Plymouth Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration