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Probiotics for antibiotic-associated diarrhoea (including Clostridium difficile) in care homes: providing incidence data on antibiotic-associated diarrhoea in care homes and evaluating care homes as a setting to conduct complex studies/drug trials

Submission date	Recruitment status	[X] Prospectively registered
06/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2016	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Taking antibiotics kills off bacteria that cause disease. However, antibiotics also kill the bacteria that help keep the harmful bacteria in check, often causing diarrhoea. Older people, especially those who are frail and have multiple health problems, are particularly prone to getting diarrhoea after taking antibiotics, including diarrhoea caused by the bacterium Clostridium difficile. Many frail elderly people live in care homes and they are often prescribed antibiotics for conditions such as urine or chest infections. Because no one knows exactly how often and what types of antibiotics are prescribed in care homes in the UK, and how often diarrhoea occurs as a consequence and how serious it is, the aim of this study is to provide this information.

Who can participate?
Residents in nine care homes

What does the study involve?
Information is collected each time a participating resident is prescribed antibiotics by their GP. If a resident who is prescribed antibiotics develops diarrhoea either during or within 8 weeks of stopping the antibiotic(s), a stool sample is collected and sent for analysis including C. difficile analysis.

What are the possible benefits and risks of participating?
The results of this study may be useful for guiding future antibiotic treatment decisions and service planning.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
October 2010 to October 2011

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. Christopher Butler

Contact information

Type(s)
Scientific

Contact name
Prof Christopher Butler

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Additional identifiers

Protocol serial number
HTA 08/13/24; SPON844-10

Study information

Scientific Title
The PAAD study: Probiotics for Antibiotic-Associated Diarrhoea (including Clostridium difficile) in care homes: establishing the platform

Acronym
PAAD

Study objectives
PAAD is a two-stage study:

Stage 1:
There is currently a lack of evidence regarding
1. The frequency of antibiotic prescribing and type of antibiotic prescribed in care homes and,
2. How often diarrhoea occurs associated with taking antibiotics (antibiotic-associated diarrhoea [AAD]), and its severity.
Therefore this study aims to provide data on the incidence of AAD including C. difficile-associated diarrhoea in care homes and if there is an issue confirm the estimated sample size for a randomised controlled trial (RCT) in Stage 2.

Stage 2 is a randomised controlled trial to assess whether AAD is prevented or ameliorated in care home service users receiving antibiotics by the administration of a probiotic alongside the antibiotic.

The information supplied here is for Stage 1 only.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/081324
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0011/52211/PRO-08-13-24.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Ethics Committee Panel B, ref: 10/WSE02/47 – approval pending

Study design
12-month observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Antibiotic-associated diarrhoea in the elderly, living in care homes

Interventions
Nine care homes in South Wales and the care home service users (residents) will be recruited for Stage 1. The main part of Stage 1 is a 12-month prospective observational study that aims to collect data (e.g. amount and type of antibiotics prescribed, episodes of antibiotic-associated diarrhoea (AAD) and Clostridium difficile-associated diarrhoea (CDAD) and outcome), in a purposive sample of care homes. Additionally, there will be three sub-studies within Stage 1.

1. Main observational study
Data regarding symptoms, indication for prescribing, type of antibiotic, dose, route of administration and duration of antibiotic will be collected each time a participating service user is prescribed antibiotics by their GP. Should a service user who is prescribed antibiotics develop diarrhoea either during or within 8 weeks of stopping the antibiotic(s), a stool sample will be collected and sent to the Public Health Wales Central Microbiology Laboratory for standard microbiological stool analysis including C. difficile analysis. A stool chart will be completed for

the duration of antibiotic treatment and for an additional 8 weeks after the antibiotic course is completed.

2. Sub-Studies
2.1. Sub Study 1: C. difficile Prevalence
A baseline stool sample will be collected from care home service users to assess C. difficile prevalence in the care homes. Data about previous antibiotic use by the service user for a 3-month period before entry to this sub-study will also be collected.

2.2. Sub Study 2: Probiotic acceptability and feasibility
This sub-study will:
2.2.1. Explore and test the acceptability, procedure and method of delivering a probiotic in conjunction with antibiotics prescribed in the course of routine care in a small number of consenting care home residents in three care homes (up to nine in total). This is to establish the procedures and prove that a probiotic can be given to this population as part of a research study according to a protocol.
2.2.2. This sub-study will also develop and pilot a training package for care home staff in implementing the possible randomised controlled trial in Stage 2.

2.3. Sub Study 3: Qualitative Study
2.3.1. Qualitative interviews will be conducted with service home users capable of consent
2.3.2. Focus groups will be conducted with family members and care home staff discussing issues around consent and assent in care home residents
2.3.3. Additional interviews with GPs regarding these issues will also be conducted.
The focus groups and interviews will also take into account issues from sub study 2 (above).

In summary, Stage 1 will identify the scale of the AAD problem in care homes, provide reliable incidence data and confirm the basis of our sample size calculation for the randomised controlled trial (RCT) in Stage 2. Stage 1 will also allow us to pilot the trial procedures and materials required for a RCT in Stage 2. If Stage 1 indicates that AAD is a rare, unimportant problem, then, based on explicit stopping rules, we will not progress to Stage 2.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Main observational study
1.1. To conduct prospective systematic ascertainment of the incidence of AAD in care homes
1.2. To allow an appraisal of the estimated sample size for a randomised controlled trial (RCT) in Stage 2

Key secondary outcome(s))
1. Main observational study
1.1. To conduct prospective systematic ascertainment of antibiotic use in care homes
1.2. To estimate the risk of AAD overall and from particular antibiotics in care home settings
1.3. To identify barriers and implementation issues in conducting a trial of AAD prevention /amelioration in a care home setting

2. Sub-studies
2.1. Sub Study 1. Prevalence:
1.1.1 To determine the prevalence of asymptomatic C. difficile carriage in service users within selected care homes.

2.2 Sub Study 2. Probiotic Feasibility and Acceptability:
2.2.1. To test the acceptability and feasibility of administering probiotics in a small number of service users
2.2.2. To pilot and develop trial procedures including modelling consent procedures
2.2.3. To develop a training package for nursing home personnel to implement the trial

2.3. Sub Study 3. Qualitative:
2.3.1. To explore the ethical and practical issues of consent and assent, particularly the topic of advanced consent, for elderly residents who may/may not have capacity to consent

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Service users who are/have been admitted to the care home for >24 hours
2. Planned admission to care home of one month or more (excludes short-term respite care)
3. Written informed consent/assent provided

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/10/2010

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/08/2013		Yes	No
Results article	results	01/10/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes