ISRCTN94786163 https://doi.org/10.1186/ISRCTN94786163

Evaluation of probiotics use for antibiotic-associated diarrhea in nursing homes

Submission date	Recruitment status	[_] Prospectively registered
03/02/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/02/2020	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
28/03/2023	Digestive System	

Plain English summary of protocol

Background and study aims
Antibiotic-associated diarrhea (AAD) occurs in 2-25% of nursing home residents, which may lead to dehydration, malnutrition, severe complications and hospitalizations. Research shows that probiotics can be effective and safe in reducing AAD. However, probiotics are not routinely used in Dutch nursing homes. The objectives of this evaluation are to develop a procedure for the implementation of probiotics to prevent AAD in nursing homes, to evaluate effects on AAD occurrence, and to evaluate the implementation process of probiotics in daily care.

Who can participate?
Nursing home residents having used either amoxicillin/clavulanic acid or ciprofloxacin.

What does the study involve?
Records of residents in nursing homes where probiotics were given with antibiotics are used to investigate the effect of the probiotics on diarrhea and compared with records of residents who were not given probiotics.

What are the possible benefits and risks of participating?
None

Where is the study run from?
1. Louis Bolk Institute (Netherlands)
2. De Alblashof, Rivas Zorggroep (Netherlands)
3. Waalburcht, Rivas Zorggroep (Netherlands)
4. Waerthove, Rivas Zorggroep (Netherlands)

When is the study starting and how long is it expected to run for?
January 2018 to February 2019.

Who is funding the study?
Winclove Probiotics BV (Netherlands)

Who is the main contact?
Dr Herman van Wietmarschen
h.vanwietmarschen@louisbolk.nl

Study website
http://www.louisbolk.org/nl/publicaties/publicatie/?pubID=3402

Contact information

Type(s)
Public

Contact name
Dr Herman van Wietmarschen

ORCID ID
https://orcid.org/0000-0003-2225-0337

Contact details
Louis Bolk Institute
Kosterijland 3-5
Bunnik
Netherlands
3981 AJ
0343523860
h.vanwietmarschen@louisbolk.nl

Type(s)
Scientific

Contact name
Dr Herman van Wietmarschen

ORCID ID
https://orcid.org/0000-0003-2225-0337

Contact details
Kosterijland 3-5
Bunnik
Netherlands
3981 AJ
0343523860
h.vanwietmarschen@louisbolk.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-003 VG

Study information

Scientific Title
Probiotics use for antibiotic-associated diarrhea: a pragmatic participatory evaluation in nursing homes

Acronym
prOud

Study objectives
Does the implementation of probiotics in nursing homes result in a reduction of antibiotics-associated diarrhea?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch ethische toetsingscommissie Brabant (Medical ethical comittee Brabant). On 25 October 2017, a statement was received from the Ethical Committee in Brabant the Netherlands (no. 2017-56), that this evaluation did not involve experiments with patients or study subjects according to the Dutch Medical Research in Human Subjects Act (WMO) and didn't require further ethics approval. The institutional review board and the client council of the Rivas Zorggroep approved the implementation and evaluation of probiotics.

Study design
Retrospective evaluation

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Antibiotics-associated diarrhea

Interventions
Data on the occurence (yes/no) of antibiotics-associated diarrhea is collected from residents taking either amoxicillin/clavulanic acid or ciprofloxacin.

In three nursing home departments, probiotics were administered together with the antibiotics. Data from these departments is compared with historical data from residents not taking probiotics from the same departments up to 27 months in the past. The elderly care physician extracted data on stool changes from the medical records and judged whether AAD occurred in each of the episodes of antibiotics use. The frequencies of AAD in the sample of residents without probiotics were compared with the sample of residents with probiotics.

Intervention Type
Supplement

Primary outcome measure
Incidence Antibiotics-associated diarrhea in the preceding 27 months, measured using patient records

Secondary outcome measures
None

Overall study start date
01/09/2017

Completion date
27/02/2019

Eligibility

Key inclusion criteria
Residents having used either amoxicillin/clavulanic acid or ciprofloxacin

Participant type(s)
All

Age group
Other

Sex
Both

Target number of participants
40 residents using probiotics and 40 control residents.

Total final enrolment
93

Key exclusion criteria
1. Not being able to swallow the probiotics
2. Not giving informed consent for using data

Date of first enrolment
01/01/2018

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
De Alblashof, Rivas Zorggroep
De Alblashof 1A
Alblasserdam
Netherlands
2951 XR

Study participating centre
Waalburcht, Rivas Zorggroep
Kleine Waal 6
Papendrecht
Netherlands
3353 BT

Study participating centre
Waerthove, Rivas Zorggroep
Kerkbuurt 200
Sliedrecht
Netherlands
3361 BM

Sponsor information

Organisation
Louis Bolk Instituut

Sponsor details
Kosterijland 3-5
Bunnik
Netherlands
3981 AJ
+31 (0)343523860
info@louisbolk.nl

Sponsor type
Research organisation

Website
https://www.louisbolk.nl

ROR
https://ror.org/02kn8an38

Funder(s)

Funder type
Industry

Funder Name
Winclove Probiotics BV

Results and Publications

Publication and dissemination plan
The study results will be disseminated in a report on the website of the research institute Louis Bolk Institute. A scientific publication will be written as well.

Intention to publish date
19/02/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. (Dr. H.A> van Wietmarschen, h. vanwietmarschen@louisbolk.nl, anonimised raw data, data is available after completion and publication of the study, data is available for 5 years after completion of the study, raw data will be published as supplementary material with the publication, the publication of the data will be in an open access journal, participants gave informed consent to use the data anonymised for 5 years).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/05/2020	15/05/2020	Yes	No
Dataset		13/05/2020	28/03/2023	No	No