

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

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| <b>Submission date</b><br>03/02/2020   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>03/02/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>28/03/2023       | <b>Condition category</b><br>Digestive System     | <input checked="" type="checkbox"/> Individual participant data                                   |

## 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?

Winlove Probiotics BV (Netherlands)

Who is the main contact?  
Dr Herman van Wietmarschen  
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## Contact information

### Type(s)

Public

### Contact name

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Scientific

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## Additional identifiers

### Protocol serial number

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 committee 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

**Study type(s)**

Prevention

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

Antibiotics-associated diarrhea

**Interventions**

Data on the occurrence (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(s)**

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

**Key secondary outcome(s)**

None

**Completion date**

27/02/2019

**Eligibility****Key inclusion criteria**

Residents having used either amoxicillin/clavulanic acid or ciprofloxacin

**Participant type(s)**

All

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**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

**ROR**  
<https://ror.org/02kn8an38>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Winlove Probiotics BV

## Results and Publications

### 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? |
|---------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results       | 13/05/2020   | 15/05/2020 | Yes            | No              |
| <a href="#">Dataset</a>         |               | 13/05/2020   | 28/03/2023 | No             | No              |
| <a href="#">Study website</a>   | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |