

# Investigation on the impact of continuous colonization of Bifidobacteria during early life on child's health

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>08/03/2016   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>11/03/2016 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>19/08/2019       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

The human gut plays host to tens of trillions of different bacteria, which are known as the "gut flora". The bacteria present in the gut flora are often referred to as "good" or "friendly" bacteria, because they assist in digestion and help to produce important vitamins for the body. One of the most common groups of bacteria that live in the gut is bifidobacteria, also known as lactic acid bacteria. Having the right levels and a good variety of gut bacteria is important for healthy development in children and good general health. It is thought that the colonization of the gut with different types of bacteria begins early in life, and can be affected by their inherited characteristics (genetic profile), how they are born (natural delivery or caesarian section) and whether they are breast fed. An initial study looked at the development of bacterial colonization in the gut by assessing faecal samples (excrement), and the components of breast milk to see if it plays a role. This follow up study is conducted when the child is aged between 4 and 7 years old aims to look at the colonization of the gut (particularly the bifidobacteria) in childhood, and whether it has an effect on the child's health.

### Who can participate?

Children aged between 4 and 7 who took part in the initial study as a baby.

### What does the study involve?

The parent/guardian of the child completes a number of questionnaires about their child's health and disease history and the child is observed by a researcher in order to assess their personality. The child also provides two faeces samples 7-9 days apart so that the levels of bacteria present in their gut, particularly bifidobacteria, can be measured.

### What are the possible benefits and risks of participating?

There are no anticipated benefits or risks for participants involved in this study.

### Where is the study run from?

Research Unit Stuivenberg (Belgium)

When is the study starting and how long is it expected to run for?  
November 2015 to September 2016

Who is funding the study?  
Yakult Honsha European Research (Belgium)

Who is the main contact?  
1. Dr Steven Ramael (scientific)  
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## Additional identifiers

**Protocol serial number**  
YAK.2.C.A.

## Study information

**Scientific Title**

The Follow-up Study of YAK.1.C.A: Investigation on the impact of continuous colonization of Bifidobacteria during early life on child's health

**Study objectives**

The aim of this study is to investigate if the presence of bifidobacteria during early life, analyzed in Study Yak.1.C.A., and its persistence impact on child's health and personality.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Commissie voor Medische Ethiek-Ziekenhuis Nervek Antwerpen, 07/04/2016

**Primary study design**

Observational

**Study design**

Single-centre observational trial

**Study type(s)**

Other

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

Intestinal microbiota

**Interventions**

Legally acceptable representative will fill out questionnaires regarding the subject's disease history and demographic as well as the Children's Behaviour Questionnaire in order to examine their personality. Two faecal samples for each subject will be collected with an interval of 7 to 9 days for microbiological analysis.

**Intervention Type**

Not Specified

**Primary outcome(s)**

The study consists of "Screening day (S)", "First faecal delivery day (F1: within 28 days after Screening day)" and "Second faecal delivery day (F2: within 7 to 9 days after F1)". Subjects will not be allowed to drink fermented milk between F1 and F2

1. Subject's disease history will be collected by questionnaire on F1, and additionally on F2 in order to follow the disease occurrence in the interval
2. Subject's demographics will be collected by questionnaire on S, and additionally on F1 and F2 in order to follow the status of fermented milk and intestinal drugs (e.g. antibiotics) ingestion in the intervals
3. Children's personality will be assessed based on Children's Behavior Questionnaire collected on F1
4. Faecal microbial composition, diversity and the absolute number of specific bacteria will be analyzed by 16S rRNA metagenomics or quantitative polymerase chain reaction (PCR) targeting bacterial DNA extracted from the faeces collected on F1 and F2. Preserved bacterial DNA from Study YAK.1.C.A. will also be analyzed.

5. Persistence of bifidobacteria from early life will be evaluated by comparing the homogeneity of bifidobacterial strains isolated from faeces collected on F2 to those isolated in Study YAK.1.C.A. by using multilocus sequence typing (MLST)

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

15/09/2016

## **Eligibility**

**Key inclusion criteria**

Male or female subjects aged between 4 and 7, who participated as a neonate in Study Yak.1.C.A.

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

4 Years

**Upper age limit**

7 Years

**Sex**

All

**Total final enrolment**

49

**Key exclusion criteria**

1. Participation in another clinical study during the study or within 30 days prior to entry in this study
2. A condition that, in the opinion of the Investigator, could compromise the well-being of the subject or course of the study, or prevent the subject from meeting or performing any study requirements

**Date of first enrolment**

21/03/2016

**Date of final enrolment**

31/07/2016

## **Locations**

## Countries of recruitment

Belgium

## Study participating centre

SGS LSS. Clinical pharmacology Unit Antwerpen

Lange Beeldekensstraat 267

Antwerpen

Belgium

2060

## Sponsor information

### Organisation

Yakult Honsha European Research Center

### ROR

<https://ror.org/03wmnrc91>

## Funder(s)

### Funder type

Industry

### Funder Name

Yakult Honsha Co., Ltd.

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Stored in repository

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 12/12/2018   | 19/08/2019 | Yes            | No              |