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

Submission date
08/03/2016

Recruitment status
No longer recruiting

Registration date
11/03/2016

Overall study status
Completed

Last Edited
19/08/2019

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 assesseing 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 involves 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)
2. Dr Junji Fujimoto (scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Nerwek Antwerpen, 07/04/2016

Study design
Single-centre observational trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure
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)

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/11/2015

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

Age group
Child

Lower age limit
4 Years

Upper age limit
7 Years

Sex
Both

Target number of participants
111 participants (maximum)

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
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Sponsor information

Organisation
Yakult Honsha European Research Center

Sponsor details
Technologiepark 4
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Sponsor type
Industry

Website
http://www.yakult.co.jp

ROR
https://ror.org/03wmnrc91

Funder(s)

Funder type
Industry

Funder Name
Yakult Honsha Co., Ltd.

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/09/2017

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?
Results article	results	12/12/2018	19/08/2019	Yes	No