

YAK.1.C.A: The colonisation of the intestine in children

Submission date 30/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/03/2016	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Plain English summary under review

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Observational single country multi-centre study of pairs of neonate and mother for analysing intestinal microbiota as well as breast milk component

Acronym

YAK.1.C.A

Study objectives

The aim of this study is to better understand how the initial colonisation of the gut occurs, which will allow a better design of new generation nutritional concepts for infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Commissie voor Medische Ethiek-ZiekenhuisNerwek Antwerpen (ZNA), Institutional Review Board-ZNA/OCMW Antwerpen approved on the 13th May 2009 (ref: 3388)

Primary study design

Observational

Study design

Single country multi-centre cohort study

Study type(s)

Screening

Health condition(s) or problem(s) studied

Intestinal microbiota

Interventions

The subjects will be selected by SGS LIFE SCIENCE SERVICES, under the supervision of the principal investigator. The principal investigator and his/her study team will cooperate with gynaecologists and midwives for the first contact with subjects. Those healthy pregnant women who agree to participate, will be included during the last 2 months of pregnancy and their newborns will be followed for 6 months. Participants will be asked to sign an informed consent, to fill in a diary and to collect faecal and breast milk samples according to the sampling protocol. For the participants the study will last at least 7 months and consists of one hospital visit and seven phone calls.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Faecal microbiota composition of the mothers and neonates. The faecal microbiota composition of the mother will be measured 2 times (with one week interval) between 1 and 2 months before the delivery. The faecal microbiota composition of the neonates will be measured in the first faecal sample of the neonates and two days later, and at one week, one month, 3 months and 6 months of life. If the baby starts with weaning food during the study period, 1 faecal sample needs to be collected 1 week after start of weaning.
2. Faecal short chain fatty acids (SCFA) and faecal lactate, measured at the same timepoints as that of the faecal microbiota
3. Microbiota composition of the breast milk. The microbiota composition of the breast milk will be measured before delivery when possible, and after delivery (colostrums) if possible, at 1 week and 1 month after delivery.

4. Oligosaccharides quantification in breast milk, measured at the same timepoints as that of the breast milk microbiota
5. Lipid quantification in breast milk, measured at the same timepoints as that of the breast milk microbiota
6. Protein quantification in breast milk, measured at the same timepoints as that of the breast milk microbiota

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/11/2011

Eligibility**Key inclusion criteria**

1. Healthy pregnant female at 24 weeks of pregnancy
2. Normal course of pregnancy
3. Written Informed Consent dated and signed by the mother
4. Good physical and mental health status as determined by medical history and general clinical examination according to the investigators judgment
5. Considered as reliable and capable of adhering to the protocol, according to the investigator

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Birth in water
2. Participation in another clinical trial during the study or within 60 days before delivery
3. Alcohol consumption of more than 7 units per week (1 unit being a glass of beer, wine or a measure of spirits)
4. Reported current usage of illegal drugs

After delivery:

1. Prematurely-born neonate (before 37 weeks of pregnancy)
2. In case a subject has decided to resign from further participation in the study
3. In case a subject suffers from a bacterial/viral infection within 2 weeks before delivery
4. In case a subject delivers a baby with major congenial malformation(s)
5. In case the subject and/or the baby use immunomodulatory drugs between 4 weeks prior to delivery and the end of the study (6 months after delivery)
6. In case the subject and/or the baby use antibiotics between 2 weeks prior to delivery and 2 weeks after the delivery, for any reason except for a prophylactic use (e.g. caesarean section)

Date of first enrolment

22/06/2009

Date of final enrolment

01/11/2011

Locations

Countries of recruitment

Belgium

Study participating centre

Research Unit Stuivenberg

Antwerp

Belgium

2060

Sponsor information

Organisation

Yakult Honsha European Research Center

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Danone Research BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

