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

Submission date 30/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/12/2009	**Overall study status** Completed	
Last Edited 11/03/2016	**Condition category** Digestive System	

Plain English summary of protocol
Plain English summary under review

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

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), Insitutional Review Board-ZNA/OCMW Antwerpen approved on the 13th May 2009 (ref: 3388)

Study design
Single country multi-centre cohort study

Primary study design
Observational

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 midwifes 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