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Microbiota diversity of infant faecal samples in Europe, Asia, Mexico and Russia

Submission date 08/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/10/2008	**Overall study status** Completed	
Last Edited 25/08/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRCT010707

Study information

Scientific Title
Microbiota diversity at the microbial species level of infant faecal samples in Europe, Asia, Mexico and Russia

Acronym
DIVERSITY

Study objectives
The faecal microflora of infants in different parts of the world have similarities despite individual variation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not required from the International Medical Ethical Committee in Wageningen as of 30/09/2008.

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Other

Study type(s)
Screening

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
Presence of pathogens or absence of "healthy" faecal microflora

Interventions
Health care staff from the Friesland Foods international network of medical specialists have agreed to participate in collecting faecal materials from Infants through their Health Care Practice. The Health Care professionals receive a reader with background information, protocols and a description of the study. Health Care professionals will be involved with coordination of sample collection and background information of the infants involved. Mothers will be asked to sign an informed consent, to collect and store faecal samples according to the sampling protocol. Samples will be transported to the Netherlands according to the sample transportation protocol. Deoxyribonucleic acid (DNA) will be extracted from the faecal samples according to the DNA extraction protocol and species will be identified and analysed according to the protocols.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Distribution of microbial species in faecal samples correlated to region.

Secondary outcome measures
Impact of geographic location on presence of microbial pathogens, and also bifidobacteria, lactobacilli, and other microbial species.

Overall study start date
04/02/2006

Completion date
01/12/2009

Eligibility

Key inclusion criteria
1. Healthy infants
2. Infants born through natural delivery
3. Informed consent
4. Infants from middle class parents
5. Exclusively formula-fed infants
6. Either male or female, aged 2 weeks up to ca. 12 months

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Weeks

Upper age limit
12 Months

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Allergic infants
2. Infants born through caesarean section

Date of first enrolment
04/02/2006

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
France

Indonesia

Mexico

Netherlands

Russian Federation

Spain

Viet Nam

Study participating centre
Pieter Stuyvesantweg 1
Leeuwarden
Netherlands
8937 AC

Sponsor information

Organisation
Royal Friesland Foods B.V. (Netherlands)

Sponsor details
c/o R. te Biesebeke
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Sponsor type
Industry

Website
http://www.frieslandfoods.com

ROR
https://ror.org/025mtxh67

Funder(s)

Funder type
Industry

Funder Name
Royal Friesland Foods B.V. (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration