

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

Submission date 08/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/08/2011	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Screening

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(s)

Distribution of microbial species in faecal samples correlated to region.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 weeks

Upper age limit

12 months

Sex

All

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)

ROR

<https://ror.org/025mtxh67>

Funder(s)

Funder type

Industry

Funder Name

Royal Friesland Foods B.V. (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration