PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Double-blind, controlled and randomised study with a parallel group design on the effect of formula feeding (IF and FOF) supplemented with a mixture of immunological active neutral and acidic oligosaccharides on the incidence of febrile respiratory and gastrointestinal infections in healthy term born infants during the first year of life.

Trial Acronym

MIPS

URL of the trial

http://nicht vorhanden

Brief Summary in Lay Language

Mothers who cannot/do not fully breastfeed their infants are randomised to one of the two formula groups. The study intervention will start at the age of 8 weeks. The active group will receive a non-hydrolysed cow`s milk based formula containing an immunomodulating mix of neutral and acidic oligosaccharides. The effects of this formula on the number of febrile episodes and symptoms of infection will be compared with the control group. This group will receive a standard non-hydrolyzed cow´s milk based formula with the same composition as the active formula but without supplementation of oligosaccharides.

Brief Summary in Scientific Language

The study will elucidate whether formula feeding (IF/FOF) supplemented with a mixture of immunomodulating neutral and acidic oligosaccharides is able to reduce the incidence of infectious illness in healthy term born infants during the first year of life as indicated by the number of febrile episodes and symptoms of infection. Mothers who cannot/do not fully breastfeed their infants are randomised to one of the two formula groups. The study intervention will start at the age of 8 weeks. The active group will receive a non-hydrolysed cow´s milk based formula containing an immunomodulating mix of neutral and acidic oligosaccharides. The effects of this formula on the number of febrile episodes and symptoms of infection will be compared with the control group. This group will receive a standard non-hydrolyzed cow´s milk based formula with the same composition as the active formula but without supplementation of oligosaccharides.

Organizational Data

- DRKS-ID: **DRKS00000201**
-

DRKS-ID: **DRKS00000201**
Date of Registration in DRKS: **2009/09/09**

- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA2/174/05 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-7779**

Health condition or Problem studied

- Free text: **Healthy, term born infants not at high risk to develop an atopic disease**
- ICD10: **Z38.2 - Singleton, unspecified as to place of birth**
- ICD10: **Z38.5 - Twin, unspecified as to place of birth**
- ICD10: **J00-J06 - Acute upper respiratory infections**
- ICD10: **J20 - Acute bronchitis**
- ICD10: **J22 - Unspecified acute lower respiratory infection**
- ICD10: **J01 - Acute sinusitis**
- ICD10: **A09 - Diarrhoea and gastroenteritis of presumed infectious origin**

Interventions/Observational Groups

- Arm 1: **exclusive administration (full formula feeding) of a standard non-hydrolysed cow`s milk based formula containing an immunomodulating mix of neutral and acidic oligosaccharides at the latest after 2 months of life until at least until the end of the 4th month of life**
- Arm 2: **Exclusive administration of a standard non-hydrolyzed cow`s milk based formula with the same composition as the active formula but without any supplementation of oligosaccharides.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

number of febrile episodes during the 1st year of life

Secondary Outcome

-Symptoms of illnesses indicating a viral or bacterial infection
-Occurrence of allergic symptoms with focus on the skin (atopic dermatitis)
-Biochemical blood/plasma parameters of immune status, at least in a subgroup of infants
-Parameters of gut health, immune status and inflammation, at least in a subgroup of infants
-Anthropometric parameters
-Parameters of safety, acceptance, tolerance and gastrointestinal discomfort

Countries of recruitment

- DE **Germany**
- NL **Netherlands**
- IT **Italy**
- AT **Austria**
- CH **Switzerland**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2005/07/19**
- Target Sample Size: **1500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **8 Weeks**

Additional Inclusion Criteria

-healthy, term born infants (GA 37-42 weeks)
-normal birth weight (girls: 2.7-5.0 kg, boys: 2.9-5.2 kg)
-not older than 8 weeks of age when entering the study,
-not at high risk to develop an atopic disease which would require the feeding of an HA formula with hydrolysed protein according to current recommendations
- no metabolic disorders requiring a special diet other than standard non-hydrolyzed IF/FOF

Exclusion criteria

-Mothers suffering from hepatitis B, HIV or GBS
-Mothers taking antibiotics during breastfeeding
-Infants with known congenital diseases or malformations which would interfere with the study, e.g. gastrointestinal malformations, congenital or acquired immunodeficiency, etc.
-Study pre-feedings of the infants which could interfere with the study, e.g. non-cow?s milk based formulas, HA formulas, probiotic formulas, etc.
-Infants with actual or previous illnesses which could interfere with the study

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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E-mail: **[---]***
URL: **http://www.milupa.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2009/04/22**

Trial Publications, Results and other documents

- Paper **JACI_Grüber et al_reduced occurence of early atopic dermatitis**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*