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Lipid content in human milk is higher in overweight/obese infants

Submission date
21/04/2022

Recruitment status
No longer recruiting

Registration date
26/04/2022

Overall study status
Completed

Last Edited
25/04/2022

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Human milk (HM) is the best nutritional source for infant to support their growth during the first 6 months. Breast-fed infants were thinner compared to formula-fed infants, but some breast-fed infants are overweight/obese.
Aim: To investigate the macronutrient content of HM in normal infants and overweight/obese infants aged <12 months old.

Who can participate?
Mothers of normal/overweight/obese infants aged 1 -12 months, who breast-fed predominantly.

What does the study involve?
The researchers collect 1.5 ml of human milk from lactating women using breast pumps in a closed room for analysis.

What are the possible benefits and risks of participating?
Benefits: Mothers will be able to predict the optimum volume of human milk for the infants to achieve optimum growth without being overweight or obese.
Risks: there is no health risk for the participants (mothers and infants)

Where is the study run from?
RSUD Dr. Soetomo (Indonesia)

When is the study starting and how long is it expected to run for?
January 2018 to April 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Nur Aisiyah Widjaja, MD
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Contact information

Type(s)
Principal investigator

Contact name
Dr Nur Aisiyah Widjaja

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
0234/KEPK/IV/2018

Study information

Scientific Title
Comparison of human milk macronutrient content between overweight and normal infants: a case-control study

Study objectives
is there a significant difference on the macronutrients content (energy, carbohydrate, protein and lipid) of human milk on overweight/obese infant (OW group) compared to normal infant (N group)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/04/2018, Health Research Ethics Committee of RSUD Dr. Soetomo Hospital (Jl. Mayjen Prof. Dr. Moestopo No. 6-8 Surabaya, Indonesia, +62 31-5501164; kepk@rsudrsoetomo.jatimprov.go.id), ref. 0234/KEPK/IV/2018

Study design
Observational case-control study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Comparison of human milk macronutrient content between overweight and normal infants

Interventions
Researchers collected the human milk using a breast pump in closed rooms at neonates wards, as much as 1.5 ml was syringed and replaced on a sterile tube with caps, and stored in an icebox until the analysis using MIRIS was performed.

The measurement of HM components was performed in the nursery room using a human milk analyzer (HMA) (MIRIS®, Uppsala, Sweden) with an accuracy of <0.1 g/100 ml.

The samples of human milk were divided into 2 groups: normal (N group) and overweight/obese (OW group) according to the nutritional status of infants, determined by a pediatrician (the researcher/Nur Aisiyah Widjaja).

Intervention Type
Other

Primary outcome(s)
Measured using a human milk analyzer (HMA) (MIRIS®) at a single time point:
1. Carbohydrate content of milk
2. Lipid content of milk
3. Energy content of milk

Key secondary outcome(s))
Measured using a human milk analyzer (HMA) (MIRIS®) at a single time point:
1. Protein content of milk

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Healthy lactating mother and does not consume steroids, drugs, alcohol, or a smoker
2. Healthy infant with nutritional status: normal, overweight or obese, aged 1-12 months old
3. Eager to participate in the study

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 months

Upper age limit
12 months

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Infants with growth deliration (underweight/ severely underweight, stunted/ severely stunted, wasted/ severely wasted)
2. Medically ill (infection, non infection)

Date of first enrolment
25/04/2018

Date of final enrolment
29/04/2018

Locations

Countries of recruitment
Indonesia

Study participating centre
RSUD Dr. Soetomo
Jl. Mayjen Prof. Dr. Moestopo No. 6-8
Surabaya
Indonesia
60286

Sponsor information

Organisation
Airlangga University

ROR
https://ror.org/04ctejd88

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date