

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

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| Submission date 21/04/2022 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/04/2022 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 25/04/2022 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 measure

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

Secondary outcome measures

Measured using a human milk analyzer (HMA) (MIRIS®) at a single time point:

1. Protein content of milk

Overall study start date

02/01/2018

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

Age group

Child

Lower age limit

1 Months

Upper age limit

12 Months

Sex

Both

Target number of participants

40

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

Sponsor details

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Jl. Mayjen Prof. Dr. Moestopo No.47
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Sponsor type

University/education

Website

<http://unair.ac.id/>

ROR

<https://ror.org/04ctejd88>

Funder(s)

Funder type

Other

Funder Name

investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/05/2022

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