

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt

Release Date: October 2, 2022

ClinicalTrials.gov ID: NCT05289674

Study Identification

Unique Protocol ID: J number

Brief Title: The Effect of Lactoferrin in High Calorie Formula on IL-6 and IL10 in Children With Failure to Thrive and Infection (Interleukin)

Official Title: The Effect of Lactoferrin in High Calorie Formula on IL-6 and IL10 in Children With Failure to Thrive and Infection

Secondary IDs:

Study Status

Record Verification: October 2022

Overall Status: Completed

Study Start: October 4, 2021 [Actual]

Primary Completion: June 30, 2022 [Actual]

Study Completion: June 30, 2022 [Actual]

Sponsor/Collaborators

Sponsor: Universitas Airlangga

Responsible Party: Principal Investigator

Investigator: Andy Darma, MD [adarma]

Official Title: Principal Investigator on Gastroenterology

Affiliation: Universitas Airlangga

Collaborators: Danone Institute International

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: 226/EC/KEPK/FKUA/2021

Board Name: Health Research Ethics Committee

Board Affiliation: Universitas Airlangga School of Medicine

Phone: +62315020251

Email: bioetik.fkua@gmail.com

Address:

Data Monitoring:

Study Description

Brief Summary: Lactoferrin is an iron-binding glycoprotein of the transferrin family which is expressed and refers to it as a "red protein from milk". It is known that lactoferrin can modulate the overall immune response in inflammatory disorders including modulation of cytokine/ chemokine production and immune regulation that resulting by interleukin (IL)-10. Children with failure to thrive have increase the risk of infectious disease. The mechanism behind this may be due to impaired of immune function, in which pro-inflammation response is increased (IL-1 β , IL-6), while IL-10 acted as anti-inflammation response tends to reduces.

High calorie formula (Oral Nutrition Supplement/ONS) are products used for oral nutrition support with the aim of increasing nutritional intake. they are a nutrition treatment option for when nutrition support has been identified beside dietary counselling. ONS are typically used in addition to a normal diet, when diet alone is insufficient to meet daily nutritional requirement due to infection or others. ONS should be treated like medication, ensure they are labelled with the patient's name and provided at the prescribed time. It is well established that nutritional deficiency or inadequate can impair immune function. Growing evidence suggest that for certain nutrients increased intake above currently recommended levels may help optimize immune function including improving the defense function and thus resistance to infection while maintaining tolerance.

This study aims to analyze the levels of IL-6 and IL-10 in children with failure to thrive with infection before and after receiving the intervention of lactoferrin in high-calorie formula milk. This study is an observational study with a pre-, post-test design, with designed total subject is 80. The subject is healthy children with weight faltering aged 1-5 years diagnosed with infection (tuberculosis/TB or urinary tract infection/UTI)

Detailed Description: Interventional study with a pre-, post-test design. After the subject were diagnosed with infection (tuberculosis/TB or urinary tract infection/ UTI), they will receive 400 kcal/day (96 g/day divided 4 times consumption) of high calorie formula prescribed by the researcher (A pediatrician) for 90 days consumption (8640 g). the subject will monitored every 30 days for acceptance, tolerance, weight increment, length increment evaluation.

The blood will be withdrawn at day 0 (before invention) and day 90 (after intervention) to measure the IL-6 and IL-10 levels. The high calorie formula is given as much as 400 kcal/day for 90 days after the subject were diagnosed with tuberculosis (TB) or urinary tract infection (UTI), determine as day 1. the diagnosis will be determined by pediatrician. Before the intervention (day 0) and after the intervention (day 61), the subjects were taken the blood by laboratory employee of the private hospital in Surabaya, Indonesia

Conditions

Conditions: Failure to Thrive
Infections

Keywords: IL-6
High Calorie Formula
Lactoferrin

Study Design

Study Type: Interventional

Primary Purpose: Supportive Care

Study Phase: N/A

Interventional Study Model: Single Group Assignment

This study is an observational study with a pre-, post-test design

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 75 [Actual]

Arms and Interventions

Arms	Assigned Interventions
<p>Experimental: Interventional study with a pre-, post-test design</p> <p>After the subject are diagnosed with infection (tuberculosis/TB or urinary tract infection/ UTI), they will receive 400 kcal/day (96 g/day divided 4 times consumption) of high calorie formula prescribed by the researcher (A pediatrician) for 90 days consumption (8640 g). the subject will be monitored every 30 days for acceptance, tolerance, weight increment, length increment evaluation.</p> <p>The blood are withdrawn at day 0 (before invention) and day 90 (after intervention) to measure the IL-6 and IL-10 levels</p>	<p>Dietary Supplement: High Calorie Formula</p> <p>The high calorie formula is given as much as 300 kcal/day for 90 days after the subject were diagnosed with tuberculosis (TB) or urinary tract infection (UTI), determine as day 1. the diagnosis were determined by pediatrician. Before the intervention (day 0) and after the intervention (day 61), the subjects were taken the blood by laboratory employee of the private hospital in Surabaya, Indonesia</p>

Outcome Measures

Primary Outcome Measure:

1. Acceptance and tolerance of high calorie formula by the subject
Change on IL-6 levels (in ng/mL), the data will be presented as mean +/- SD. The level of IL-6 will be investigated using human IL-6 ELISA kit (BT Lab)
[Time Frame: 90 days]
2. Acceptance and tolerance of high calorie formula by the subject
Change on IL-10 (in ng/mL), the data will be presented as mean +/- SD. The level of IL-10 will be investigated using human IL-10 ELISA kit (BT Lab)
[Time Frame: 90 days]

Secondary Outcome Measure:

3. Acceptance and tolerance of high calorie formula by the subject
Change on body weight (in kg) the data will be presented as mean +/- SD. The body weight will be measure using digital baby scale (Seca 354) and digital scale Seca Robusta 813.
[Time Frame: 90 days]
4. Acceptance and tolerance of high calorie formula by the subject

Change on body length/body height (in cm). The body length/height will be measure using infantometer (Seca 416) and stadiometer (for children aged < 2 years, Seca 213)

[Time Frame: 90 days]

Eligibility

Minimum Age: 1 Years

Maximum Age: 5 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Children aged 1 - 5 years were diagnosed with failure to thrive with infections (TB or UTI)

Exclusion Criteria:

- Fluid retention
- Organomegaly
- Tumor mass
- Congenital abnormalities
- Cerebral Palsy
- Hormonal disorders and syndrome

Drop out Criteria:

- Lost contact

Contacts/Locations

Central Contact Person: Nur Aisiyah Widjaja, Doctor
Telephone: +628123073379
Email: nur.aisiyah.widjaja-2017@fk.unair.ac.id

Central Contact Backup: Soebagijo Adi Soelistijo, OBGYN specialist
Telephone: +628123531065
Email: kepk@fk.unair.ac.id

Study Officials:

Locations: **Indonesia**

Husada Utama Hospital

Surabaya, East Java, Indonesia, 60131

Contact: Didi Darmahadi Dewanto, OBGYN specialist +62315018335
info@husadautamahospital.com

Contact: Nur Aisiyah Widjaja, Doctoral +62315020251
nur.aisiyah.widjaja-2017@fk.unair.ac.id

Husada Utama Hospital

Surabaya, East Java, Indonesia, 60131

Contact: Didi Darmahadi Dewanto, OBGYN specialist +62315018335
info@husadautamahospital.com

Contact: Nur Aisiyah Widjaja, Doctoral +62315020251
nur.aisiyah.widjaja-2017@fk.unair.ac.id

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information: