Aug 20, 2020 Version 1

Comparison of Two Fat Emulsions on Interleukin-1β, Interleukin-8 and Fatty Acid Composition in Infants Post Gastrointestinal Surgery: A Randomized Trial Protocol V.1

DOI
https://dx.doi.org/10.17504/protocols.io.bjzdkp26

Meta Herdiana Hanindita[1]

[1]Doctoral Program, Faculty of Medicine, Universitas Airlangga

metahanindita

DOI: https://dx.doi.org/10.17504/protocols.io.bjzdkp26

Protocol Citation: Meta Herdiana Hanindita 2020. Comparison of Two Fat Emulsions on Interleukin-1β, Interleukin-8 and Fatty Acid Composition in Infants Post Gastrointestinal Surgery: A Randomized Trial Protocol. **protocols.io** https://dx.doi.org/10.17504/protocols.io.bjzdkp26

Protocol status: Working
We use this protocol and it's working

Created: August 20, 2020

Last Modified: August 20, 2020

Protocol Integer ID: 40709

Keywords: enriched intravenous fat emulsion, intravenous fat emulsion, standard intravenous fat emulsion, intravenous lipid emulsion, based fat emulsion, fat emulsion, two fat emulsion, comparison of two fat emulsion, fatty acid, lct fat emulsion, fatty acid composition, total fatty acid, integral part of parenteral nutrition, type of emulsion, acid composition in infant, parenteral nutrition, inflammatory eicosanoid, generating inflammatory eicosanoid, infants post gastrointestinal surgery, emulsion, severe inflammatory response, inflammatory, structure modification of fatty acid, interleukin, cytokine, crucial role in pediatric patient, excessive cytokine secretion, linoleic acid, such as prostaglandine e3, linolenic acid, postoperative sepsis, high levels of linoleic acid, gastrointestinal surgery3, eicosapentaenoic acid, protocol surgical intervention in infant, severe outcomes due to immature immune system1, long chain triglyceride, immature immune system1, arachidonic acid, doxohexanoic acid, gastrointestinal sur

Abstract

Surgical intervention in infants is associated with postoperative sepsis and severe outcomes due to immature immune system[1]. Gastrointestinal surgery induces excessive cytokine secretion, which may lead to increased postoperative mortality and morbidity[2].
Parenteral nutrition plays a crucial role in pediatric patients who undergo gastrointestinal surgery[3]. Intravenous lipid emulsion is an integral part of parenteral nutrition because it contains high energy density and low osmolarity, hence becoming the main source of energy and essential fatty acids[4,5]. Fatty acid determines structural integrity and fluidity of cell membrane, and it has been proven that fatty acid helps to regulate expression of various genes and modulate cell-signaling pathway, which occurs during inflammation[6,7].
The current standard type of IVFE is a 50:50 mixture of medium chain triglyceride (MCT) and long chain triglyceride (LCT)[8]. This type of emulsion is rich in ω-6 and contains high levels of linoleic acid (LA, C18:2 ω -6) and alpha-linolenic acid (ALA, C18:3 ω-3). According to several studies, ω-6 is associated with impaired cell-mediated immunity and higher potential risk of elevated proinflammatory markers and severe inflammatory response. This mechanisms may lead to the increase in mortality, morbidity, duration of treatment, and recovery time in patients who undergo gastrointestinal surgery[9-11].
Calder (2010) showed that the structure modification of fatty acids may alter their functions7. Some studies have shown that the addition of ω-3 in soy oil-based fat emulsion may improve patients' outcome by modulating inflammatory response[3,4,12]. ω-3, particularly eicosapentaenoic acid (EPA) and doxohexanoic acid (DHA), is a competitive enzyme inhibitor of arachidonic acid (AA). ω-3 has potential anti-inflammatory properties by inhibiting AA pathway and generating inflammatory eicosanoids, such as prostaglandine E3, thromboxane A3 and leukotriene B5, which are considered less inflammatory. Up to this time, the effect of ω-3-enriched intravenous fat emulsion compared to standard intravenous fat emulsion on the IL-1b ,IL-8 levels and plasma fatty acid composition in infants who undergo gastrointestinal surgery has yet to be elucidated.
The purpose of this study is aimed to investigate the effect of ω-3-enriched intravenous fat emulsion compared to standard intravenous fat emulsion on the IL-1b ,IL-8 levels and plasma fatty acid composition in infants who undergo gastrointestinal surgery

Trial Design:
Type: Parallel randomized controlled trial
Allocation ratio:1:1
Framework: Superiority

Aim of the study:
The purpose of this study is to investigate the effect of ω-3-enriched intravenous fat emulsion compared to standard MCT/LCT intravenous fat emulsion on the IL-1b ,IL-8 levels and plasma fatty acid composition in infants who undergo gastrointestinal surgery.

PICO approach:
P: Patients underwent gastrointestinal surgery.
I: ω-3-enriched intravenous fat emulsion
C: MCT/LCT standard intravenous fat emulsion

O:

		Outcome measure	Tool for measurement	Unit of measurement
	Primary	Inflammatory response IL-1	Blood	pg/ml
		Inflammatory response IL-8	Blood	Pg/ml
	Secondary	Fatty Acid composition	Blood	(%of Total fatty acids)

S→ Randomized control study

Research Question
Will the Intravenous omega-3 enriched-fat emulsion make difference in IL-1β, IL-8 and fatty acid composition when compared to standard intravenous MCT/LCT fat emulsion?

Attachments

Protokol.docx
678KB

Materials

MATERIALS

Interleukin-1beta **R&D Systems**

Interleukin-8 **R&D Systems**

Primary Outcome (p): IL-1β, IL-8

IL-1β, IL-8 levels will be measured by Quantikine HS ELISA R& D System before surgery and 3 days after surgery.

Secondary outcome (Fatty Acid Composition)

The profiling of fatty acid composition was analyzed using gas chromatography tandem mass spectrometry (GC-MSMS) before surgery and 3 days after surgery.

Safety warnings

Allergy reaction: rash

Before start

A-The experimental group (ω-3-enriched intravenous fat emulsion)

1-The parents or the legal guardian of patients who fulfill the inclusion and exclusion criteria will have to sign informed consent after the investigator explains the study.
2-Before surgery, blood samples of patients will be drawn (3-4 cc) in order to examine their IL-1β, IL-8 levels and plasma fatty acid composition.
3-After surgery, patients will get ω-3-enriched intravenous fat emulsion (SMOFlipid) for three consecutive days in 1-4 gram/kilogram/day dosing.
4-On day three after surgery, blood samples of patients will be drawn (3-4 cc) in order to examine their IL-1β, IL-8 levels and plasma fatty acid composition post-treatment.
5-All of blood samples will be sent to Prodia laboratory.

B-The control group (MCT/LCT standard intravenous fat emulsion)

1- The parents or the legal guardian of patients who fulfill the inclusion and exclusion criteria will have to sign informed consent after the investigator explains the study.
2- Before surgery, blood samples of patients will be drawn (3-4 cc) in order to examine their IL-1β, IL-8 levels and plasma fatty acid composition.
3- After surgery, patients will get ω-3-enriched intravenous fat emulsion (SMOFlipid) for three consecutive days in 1-4 gram/kilogram/day dosing.
4- On day three after surgery, blood samples of patients will be drawn (3-4 cc) in order to examine their IL-1β, IL-8 levels and plasma fatty acid composition post-treatment.
5- All of blood samples will be sent to Prodia laboratory.