Sep 02, 2020

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

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1 Works for me dx.doi.org/10.17504/protocols.io.bknmkvc6

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ABSTRACT

Surgical intervention in infants is associated with postoperative sepsis and severe outcomes due to immature immune system1. Gastrointestinal surgery induces excessive cytokine secretion, which may lead to increased postoperative mortality and morbidity2.
Parenteral nutrition plays a crucial role in pediatric patients who undergo gastrointestinal surgery3. 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 acids4,5. 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 inflammation6,7.
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 surgery9-11.
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 response3,4,12. 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.

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?

Citation: Meta Herdiana Hanindita (09/02/2020). Comparison of Two Lipid Emulsions on Interleukin-1ÃÂ², Interleukin-8 and Plasma Fatty Acid Composition in Infants Post Gastrointestinal Surgery: A Randomized Trial. https://dx.doi.org/10.17504/protocols.io.bknmkvc6

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

	Outcome	Tool for Measurement	Unit of Measurement
Primary	Inflammatory Response: IL-1b, IL-8	Blood	pg/ml
	Fatty Acid Composition	Blood	% Total Fatty Acid
Secondary	Laboratory parameters: Hemoglobin	Blood	g/dL
	Laboratory parameters: Leukocyte	Blood	/microL
	Laboratory parameters: Albumin	Blood	g/L
	Laboratory parameters: CRP	Blood	mg/L

ATTACHMENTS

Protocol.docx

DOI

dx.doi.org/10.17504/protocols.io.bknmkvc6

PROTOCOL CITATION

Meta Herdiana Hanindita 2020. Comparison of Two Lipid Emulsions on Interleukin-1β, Interleukin-8 and Plasma Fatty Acid Composition in Infants Post Gastrointestinal Surgery: A Randomized Trial. **protocols.io** https://dx.doi.org/10.17504/protocols.io.bknmkvc6

CREATED

Sep 02, 2020

LAST MODIFIED

Sep 02, 2020

PROTOCOL INTEGER ID

41389

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. Laboratory parameters will also be examined.
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. Laboratory parameters will also be examined.
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.Laboratory parameters will also be examined.
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. Laboratory parameters will also be examined.
5- All of blood samples will be sent to Prodia laboratory.

MATERIALS

NAME	CATALOG #	VENDOR
Interleukin-1beta		R&D Systems
Interleukin-8		R&D Systems

MATERIALS TEXT

Reagents used in this study were FAME Standard Mix (Supelco), GLC Nonadecanoic ISTD (Supelco), N-Hexane MS grade (Merck), Chloroform (Merck), Methanol Hyper Grade (Merck), Capillary Column and Helium Gas for GCMS.

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