Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of high dose interalipid administration versus its gradual increase in neonates weighing less than 1500

Protocol summary

Study aim

study of the effect of high dose interalipid administration versus its gradual increase in preterm infants weighing less than 1500

Design

Study is randomized and patients were randomly divided into two parallel control and intervention groups (clinical trial). Randomization type is simple randomization and randomization unit were individual. Individuals were randomly divided into two groups of control and study.

Settings and conduct

Study is randomized, not blinded. 104 neonates born at Akbar abadi Hospital with very low birth weight (below 1500g) We divide into equal weight groups in weight groups and start with an injectable lipid emulsion from 1 g / kg per 24 hours and increase 1 gram daily to 3 grams per kilogram per 24 hours.In the other group, we will give a dose of 3 grams per kilogram from the beginning. Then, newborns are checked daily for blood glucose and weight. ABG is taken twice a week and triglycerides and CRP are performed. In cases of suspected sepsis, blood cultures are sent and we will monitor neonates until they are fed with milk up to 100 cc per kilogram of weight .

Participants/Inclusion and exclusion criteria

All neonates born in Akbar Abadi Hospital with a birth weight of less than 1500 grams who had no major anomalies and perinatal asphyxia (Apgar 5 minutes below 6) and had no sepsis. parents had a written consent for entry into the study. If parents are not willing to continue their studies or if there is any evidence of sepsis or metabolic acidosis, or high-triglyceride over 200 or glucose more than 200 three times or hypoxia less than 85% that treated with intralipid interruption, the study is finished and the baby is excluded from the study.

Intervention groups

104 neonates born at Akbarabadi Hospital with very low birth weight (below 1500g) We divide into equal weight groups in weight groups and start with an injectable lipid emulsion from 1 g / kg per 24 hours and increase 1 gram daily to 3 grams per kilogram per 24 hours.In the other group, we will give a dose of 3 grams per kilogram from the beginning.

Main outcome variables

Effect of high dose interalipid administration versus its incremental to blood glucose and weighting and ABG and TG and CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160120026115N6**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **retrospective**

Last update: **2018-02-17, 1396/11/28**
Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Mandana Kashaki

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 2277

Email address

kashakimd@gmail.com

Recruitment status

Recruitment complete

Funding source

All costs are provided by the public sector (annual repayment of Iran University of Medical Sciences)

Expected recruitment start date
2016-03-20, 1395/01/01
Expected recruitment end date
2017-03-21, 1396/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of high dose interalipid administration versus its gradual increase in neonates weighing less than 1500

Public title
Evaluation of the effect of high dose interalipid administration versus its gradual increase in neonates weighing less than 1500
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All children born in Akbar Abadi Hospital with a birth weight of less than 1500 grams. Had no perinatal asphyxia (Apgar 5 minutes below 6). Parents had a written consent for entry into the study. Had no major anomalies.
Exclusion criteria:
If there is any evidence of sepsis before randomization If there is any evidence of metabolic acidosis before randomization hypoxia less than 90% before randomization
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization type is simple randomization and randomization unit were individual. Individuals were randomly divided into two groups of control and study.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Road, Tehran
City
Tehran
Province
Tehran
Postal code
1494868871
Approval date
2017-01-28, 1395/11/09
Ethics committee reference number
IR.IUMS.REC1395.9311165004

Health conditions studied

1

Description of health condition studied
advising of high doses interalipid
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Triglyceride
Timepoint
Before the intervention, then twice a week
Method of measurement
laboratory kit

2

Description
Arterial blood gas analysis and blood bicarbonate
Timepoint
Before the intervention, then twice a week
Method of measurement
laboratory kit

3

Description
Blood glucose
Timepoint
Before the intervention and then daily
Method of measurement
laboratory kit

4

Description
neonate weight
Timepoint
Before the intervention and then daily
Method of measurement
Scales

5

Description
CRP
Timepoint
Before the intervention, then twice a week
Method of measurement
laboratory kit

Secondary outcomes

1

Description
blood culture
Timepoint
Before intervention and then if symptoms of sepsis occur
Method of measurement
Observation of microbial growth in culture media

Intervention groups

1

Description
Control group: this group started with an injectable lipid emulsion from 1 gr / kg per 24 hours and increase 1 gram daily to 3 grams per kilogram per 24 hours . We monitor neonate with milk feeding until 100 cc / kg Or up to one month old (each one will arrive sooner).
Category
Treatment - Drugs

2

Description
Intervention group: In the other group, initially, an interlipid dose of 3 grams per kilogram for 24 hours recommended.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Abadi Hospital Tehran
Full name of responsible person
Mandana Kashaki
Street address
Akbar Abadi Hospital, Molav Ave
City
Tehran
Province
Tehran
Postal code
1494868871
Phone
+98 21 4474 0360
Email
kashakimd@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Iran University of Medical Sciences
Full name of responsible person
Leili Irani
Street address
Iran University of Medical Sciences, Hemmat highway
City
Tehran
Province
Tehran
Postal code
1494868871
Phone
+98 21 4474 0360
Email
kashakimd@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mandana Kashaki
Position
Assistant Professor

Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
hemmat high way, Tehran
City
Tehran
Province
Tehran
Postal code
1494868871
Phone
+98 21 5563 2277
Fax
+98 21 5563 2277
Email
kashakimd@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Akbar Abadi Hospital
Full name of responsible person
Mandana Kashaki
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Street address
Shahid Akbar Abadi Hospital; molavi Ferdows Station; tehran
City
tehran
Province
Tehran
Postal code
1494868871
Phone
+98 21 5563 2277
Fax
Email
kashakimd@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Babak Jafarvand
Position
Pediatric Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Shahid Akbar Abadi hospital, Ferdowsi Station, Molavi st.
City
Tehran
Province
Tehran
Postal code
1494868871
Phone
+98 21 4474 0360
Fax
Email
babakjafarvand1363@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people.
When the data will become available and for how long
The start of the access period is 6 months after the results are printed.
To whom data/document is available
Data will only be available to researchers in academia.
Under which criteria data/document could be used
Other conditions for the use of data or documentation are those who have been approved by scholars working in academic and scientific institutions.
From where data/document is obtainable
Doctor Mandana Kashaki tel:09123580373 kashakimd@gmail.com Doctor Babak Jafarvand tel:09122833963 babakjafarvand@gmail.com
What processes are involved for a request to access data/document
The start of the access period is 6 months after the results are printed. Data will only be available to researchers in academia. Other conditions for the use of data or documentation are those who have been approved by scholars working in academic and scientific institutions.
Comments