

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of oral supplement of carnitine on hypoglycemia, sepsis and apnea of very low birth weight neonates

Protocol summary

Summary

Premature neonates often are at risk of developing carnitine deficiency because of immaturity of the biosynthetic pathway, lack of sufficient predelivery transplacental transport, and lack of sufficient exogenous supplementation. Systemic carnitine deficiency may present with apnea, hypotonia, and poor growth. The aim of this study was to determine the effect of oral carnitine supplementation on hypoglycemia, sepsis and apnea of very low birth weight neonates. Sixty preterm neonates who were <1500 g were enrolled in this prospective, double-blind study within first 72 hours of life. Hypoglycemia, sepsis and episodes of apnea are the primary outcome measures. Neonates were allocated to intervention and control groups (30 in each group). Intervention group received 20mg/kg/day carnitine by N/G tube until 11th day of birth. Episodes of apnea were measured by pulse oxymetry, hypoglycemia by glucometer and sepsis by result of blood culture.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707281162N6**

Registration date: **2008-10-29, 1387/08/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2008-10-29, 1387/08/08

Registrant information

Name

Ashraf Mohammadzadeh

Name of organization / entity

Neonatal Research Center of Mashhad University of

Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2007-03-05, 1385/12/14

Expected recruitment end date

2008-11-06, 1387/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral supplement of carnitine on hypoglycemia, sepsis and apnea of very low birth weight neonates

Public title

Effect of oral supplement of carnitine on hypoglycemia, sepsis and apnea of very low birth weight neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion/Exclusion: Neonates with appropriate for gestational age, birth weight < 1500g, in 3 days of life, without cardiovascular disease, congenital anomaly and respiratory or metabolic diseases. Exclusion: History of diabetes, hypertension, preeclampsia or long fever in mother. Mechanical ventilation, severe hypotension, shock, metabolic disease during the intervention for neonates.

Age

To 3 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**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**

vice chancellor of mums

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ghoreshi bulding-daneshgah street-mashhad-Iran

City

mashhad

Postal code

91379-13131

Approval date

2007-03-05, 1385/12/14

Ethics committee reference number

22798/824

Health conditions studied**1****Description of health condition studied**

Carnitine supplementation in very low birth weight neonates

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Septicemia

Timepoint

Daily

Method of measurement

Positive blood culture

2**Description**

Hypoglycemia (serum glucose less than 40 mg/dl)

Timepoint

daily

Method of measurement

glucometer

3**Description**

Apnea

Timepoint

Daily

Method of measurement

Number of apnea episodes (by pulsoximetry)

Secondary outcomes**1****Description**

Duration of admission in hospital

Timepoint

daily

Method of measurement

Number of hospitalization days

Intervention groups**1****Description**

carnitine supplementation (20mg/kg/day) up to 11th day of birth

Category

empty

Recruitment centers**1****Recruitment center****Name of recruitment center**

NICU Emaereza hospital-Neonatal Research Centerdr.

Full name of responsible person

Ashraf Mohammadzadeh

Street address

Neonatal Research Center- NICU- Emamreza hospital-mashhad-Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Street address

City

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Neonatal Research Center

Full name of responsible person

Dr.Ashraf mohammadzadeh

Position

Neonatologist, professor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty