Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of oral carnitine supplement in apnea of prematurity in the NICU of sums related hospitals

Protocol summary

Summary

Apnea is a common commorbity in preterm infants who admitted in NICU That causes increased hospital stay and treatment expenditure. In addition preterm infants are at high risk of carnitine deficiency with manifistations of apnea, hypotonia and poor growth. so we decided to study the effect of oral carnitine supplement in apnea of preterm infants in the NICU of sums related hospitals. This study is a comparative, randomized, prospective clinical trials in 112 preterm infants including of birth weight≤1500 gr or gestational age ≤32 weeks. That divided to two grops, one is control with peacebo and another is study group with oral carnitine supplement (100mg/kg/day).That begun in 2nd or 3rd day of life and continues for 2 weeks. During this period, we monitor the preterm infants for developing apnea, and bradycardia. Then after evaluated the result . any infants with sever congenital anomalies, genetic and chromosomal abnormalities, inborn error of metabolism, severe IVH, sever liver disease, sepsis are excluded from the study.

General information

Acronym

The effect of oral carnitine supplement in apnea of prematurity

IRCT registration information

IRCT registration number: **IRCT2013052010441N2**
Registration date: **2013-06-28, 1392/04/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-28, 1392/04/07

Registrant information

Name

Narjes Pishva

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1612 5481

Email address

pishvan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz neonatal research center

Expected recruitment start date

2012-08-10, 1391/05/20

Expected recruitment end date

2013-07-11, 1392/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral carnitine supplement in apnea of prematurity in the NICU of sums related hospitals

Public title

The effect of oral carnitine supplement in apnea of prematurity in the NICU of sums related hospitals

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: all newborn infants who have a gestational age of ≤32 week or have birth weight of≤1500 gr. Exclusion criteria: any neonate with sever congenital anomalies; genetic and chromosomal abnormalities; inborn error of metabolism; severe IVH; sever liver disease and sepsis.

Age
From **2 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences Ethics Committee
Street address
Shiraz University of Medical Sciences, Zand street
City
Shiraz
Postal code
0711
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
CT- 92-6497

Health conditions studied

1

Description of health condition studied
Apnea in preterm infants
ICD-10 code
P28.4
ICD-10 code description
Other apnoea of newborn

Primary outcomes

1

Description
Apnea in preterm infants
Timepoint
2 days to 2 weeks
Method of measurement
monitoring

Secondary outcomes

1

Description
Episodes of apnea and growth indices in the infants
Timepoint
2 days to 2 weeks
Method of measurement
Monitoring

Intervention groups

1

Description
intervention:Neonates were randomly assigned to receive oral carnnitine (100mg/kg/day) divided in q12hr,that were initiated within 72 hours of birth and recording episods of apnea and bradycardia and side effects of carnitine in q8hr
Category
Treatment - Drugs

2

Description
in control group: receive oral placebo (with the same amount in volume) initiated within 72 hours of birth and recording of apnea episods q8hr . finally interpreting the result
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz University of Medical Science related hospital
Full name of responsible person
Dr. Pishva
Street address
Fars, Shiraz, Zand street Nemazee Hospital
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Gholam reza Hatam
Street address
7th floor dean of research Fars, Shiraz, Zand street building of university of medical science
City
shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Bolod Soleimani
Position
MD,Neonatal fellowship
Other areas of specialty/work
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
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Dr. Narjes pishva/ Dr.Fariba Hemmati
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MD, Neonatal super specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Dasht Peyma
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Researcher of neonatal research center
Other areas of specialty/work
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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