

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 commorbidity 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 manifestations 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 groups, one is control with placebo 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 severe congenital anomalies, genetic and chromosomal abnormalities, inborn error of metabolism, severe IVH, severe 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 severe congenital anomalies; genetic and chromosomal abnormalities; inborn error of metabolism; severe IVH; severe 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 carnitine (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 address7th 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**Street address**

Nemazee hospital, zand street, shiraz

City

Shiraz

Postal code

7193711354

Phone

+98 71 1612 5481

Fax

+98 71 1647 4298

Email

soleimani_b@sums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Narjes pishva/ Dr. Fariba Hemmati

Position

MD, Neonatal super specialist

Other areas of specialty/work**Street address**

Nemazee hospital zand street, shiraz

City

shiraz

Postal code

71937-11354

Phone

+98 71 1612 5481

Fax

+98 71 1647 4298

Email

pishvan@sums.ac.ir, hemmatif@sums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Dasht Peyma

Position

Researcher of neonatal research center

Other areas of specialty/work**Street address**

Neonatal research center, Nemazee hospital, zand street

City

Shiraz

Postal code

71937-11354

Phone

+98 71 1612 5481

Fax**Email**

marziehdashtpeyma@yahoo.com

Web page address**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*