Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Restricted fluid volume with Standard Fluid volume In management of Transient Tachypnea Of Newborn

Protocol summary

Study aim
Comparison of Restricted fluid volume with Standard Fluid volume In management of Transient Tachypnea Of Newborn

Design
clinical trial,with control group,based on social and actual ,with a paralel group,single blind ,rondomised

Settings and conduct
This study was done in Besat and Fatemieh hospitals during 15 months. In two groups(standard and study) check lists completed and data were analysed.single blind considered for standard group.

Participants/Inclusion and exclusion criteria
Newborns with gestational age 37 to 41 with Transient Tachypnea of Newborn that are hospitalized in 3 first days of birth .Exclusion criteria: Critical events of perinatal problems include congenital malformations ,systemic infection (confirmed by positive blood culture) ,meconium aspiration ,respiratory distress syndrome(confirmed by graphy),intrauterine growth retardation, pneumonia, congenital heart disease, multi organ failure, DIC, hypocalcemia, hypoglycemia, polycytemia, , Na> 150,Bun>20,K>5,Urine volume <1cc/kg/hr

Intervention groups
Newborns with gestational age 37 to 41 with Transient Tachypnea of Newborn that are hospitalized in 3 first days of birth .

Main outcome variables
Transient Tachypnea of Newborn ; restricted fluid therapy; O2 therapy with hood; O2 therapy with N-CPAP; O2 therapy with ventilator

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120925010933N10**
Registration date: **2018-02-01, 1396/11/12**
Registration timing: **retrospective**

Last update: **2018-02-01, 1396/11/12**
Update count: **0**

Registration date
2018-02-01, 1396/11/12

Registrant information

Name
Fatemeh Eghbalian

Name of organization / entity
Hamadan University of Medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1822 3978

Email address
eghbalian@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-02-20, 1394/12/01

Expected recruitment end date
2017-10-23, 1396/08/01

Actual recruitment start date
2016-02-20, 1394/12/01

Actual recruitment end date
2017-10-23, 1396/08/01

Trial completion date
empty

Scientific title
Comparison of Restricted fluid volume with Standard Fluid volume In management of Transient Tachypnea Of Newborn

Public title

Effect of fiuid therapy on Transient Tachypnea of Newborn

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria : Newborns with gestational age 37 to 41 with Transient Tachypnea of Newborn that are hospitalized in 3 first days of birth

Exclusion criteria:
معیار های خروج از مطالعه : وجود حوادث وخیم پری ناتال نوزادان شامل ناهنجاری های مادر زادی، عفونت سیستمیک اثبات شده (کشت خون مثبت) ،اسپیراسیون مکونیوم،سندرم دیسترس تنفسی(بر اساس گرافی)، تاخیر رشد داخل رحمی، پنومونی، بیماری مادرزادی نارسایی چند ارگانی،انعقاد داخل عروقی منتشر، هیپوکالسمی،هیپو گلیسمی،پلی قلبی ، ادرارکمتراز1سی سی5< K ،20< Bun ،150< Naسایتمی، حجم پر کیلو گرم در ساعت

Age
From **148 days** old to **287 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized

Blinding (investigator's opinion)
Single blinded

Blinding description
Control group(standard) of fluid therapy:In standard group that recieved standard fluid therapy ,didnot have information about this research

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan Univercity Of Medical Sciencse

Street address
Shahid Fahmide Ave,Hamadan Univercity Of Medical Sciencse, Hamedan, Iran

City
Hamadan

Province
Hamadan

Postal code
6516837634

Approval date
2016-06-11, 1395/03/22

Ethics committee reference number
IR.UMSHA.REC.1395.153

Health conditions studied

1

Description of health condition studied
Transient tachypnoea of newborn

ICD-10 code
P22.1

ICD-10 code description
Transient tachypnea of newborn

Primary outcomes

1

Description
Transient Tachypnea Of Newborn

Timepoint
daily

Method of measurement
observation and record of respirtory rate per minute

Secondary outcomes

1

Description
O2 requirement

Timepoint
daily

Method of measurement
per liter. per minute

2

Description
hospitalization

Timepoint
date of discharge

Method of measurement
day

Intervention groups

1

Description
Intervention group: First interventional group(control group) : Newborn with gestational age 37 to 41weeks and receipt srandard fluid therapy.second interventional group(study group) : Newborn with gestational age 37 to

41weeks and receipt restricted fluid therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital- - Neonatal Ward

Full name of responsible person

Dr. Fatemeh Eghbalian

Street address

Besat hospital, Motahari Ave, Hamedan, Iran.

City

hamadan

Province

Hamadan

Postal code

651484411

Phone

+98 81 3264 0020

Email

eghbalian@umsha.ac.ir

2

Recruitment center

Name of recruitment center

fatemieh hospital

Full name of responsible person

Dr.fatemeh eghbalian

Street address

pasdaran street

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7082

Email

eghbalian@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Eghbalian

Street address

Mahdie Ave, Hamadan University of Medical Sciences,Hamadan,Iran

City

hamadan

Province

Hamadan

Postal code

32640020

Phone

+98 81 3264 0020

Email

Eghbalian@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr.eghbalian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Neonatal Ward, Besat hospital, Motahari Ave, Hamedan, Iran.

City

Hamadan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3264 0020

Email

eghbalian@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr.fatemeh eghbalian

Position

Professor

Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Neonatal Ward, Besat hospital, Motahari Ave, Hamedan, Iran.
City
hamadan
Province
Hamadan
Postal code
6514845411
Phone
+81 32640020
Email
eghbalian@umsha.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr.fatemeh eghbalian
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Bessat Hospital, Motahari Ave, Hamedanl Iran
City
hamadan
Province
Hamadan
Postal code
6514845411
Phone
+81 32640020
Email
eghbalian@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available