

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of limitation of fluid in treatment of transient tachypnea of newborn

Protocol summary

Summary

Object: the effects of fluid restriction of fluid in treatment of transient tachypnea of newborn. Design: double blind randomized clinical trial with a control group. Intervention & method: for 70 preterm, term and post term infants have TTN divide in two groups randomly, Control group with standard fluid regime administration (65ml/kg/d) and case group with (50ml/kg/d) fluid reception. In the following days in each group in the absence of contraindications Daily (20ml / kg/d) is added to the liquid volume. Inclusion criteria: The late preterm and term and post term neonates with tachypnea (Respiratory Rate greater than 60 per minute) with or without respiratory distress. Exclusion criteria: Preterm neonates; neonates with history of asphyxia; RDS; Air-block syndrom; birth trauma; congenital anomaly and; blood culture positive; receive surfactants; develop dehydration complication. Main outcome measure: reduce of respiratory rate; reduce of hospitalization; improvement of Retraction Score; improvement of Artrial Gases; reduce of O2 requirement

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122225650N1**

Registration date: **2016-03-07, 1394/12/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-07, 1394/12/17

Registrant information

Name

Mitra Gorji Rad

Name of organization / entity

Babol Medical Sciences University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Babol University of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of limitation of fluid in treatment of transient tachypnea of newborn

Public title

The effect of restriction of fluid in treatment of transient tachypnea of newborn

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The late preterm (gestational age of 34 – 37 weeks) and term (gestational age of 37 -42 weeks) and post term (gestational age greater than 42 weeks) neonates with tachypnea (Respiratory Rate greater than 60 per minute) with or without respiratory distress within 6 hours of birth. Exclusion criteria: Preterm neonates

(gestational age less than 34 weeks); neonates with history of asphyxia;RDS;air-block syndrom; birth trauma; congenital anomaly and neonates with blood culture positive and also infants who receive surfactants while treatment or develop dehydration complication (weight loss more than one percent daily, reduce urine outflow to lower than (1cc /kg /hour) or increase urine specific gravity more than(1/017) have excluded from study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

The patient selective alternatively

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee OF Babol University of Medical

Street address

Ganjafrooz street

City

Babol

Postal code**Approval date**

2015-10-20, 1394/07/28

Ethics committee reference number

MUBABOL.REC.1394.8

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

Transient tachypnea of newborn

ICD-10 code

P22.1

ICD-10 code description

Transient tachypnea of newborn

Primary outcomes**1****Description**

Tachypnea

Timepoint

daily

Method of measurement

observation and record of respiratory rate per minute

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

reduce of hospitalization

Timepoint

date of discharge

Method of measurement

day

2**Description**

Retraction Score

Timepoint

daily

Method of measurement

Observation and record on bases of SILVERMAN - ANDERSON Retraction Score

3**Description**

respiratory rate

Timepoint

daily

Method of measurement

observation and record of respiratory rate per minute

4**Description**

Arterial Blood Gases

Timepoint

daily

Method of measurement

Blood sample

5**Description**

O2 requirement

Timepoint

daily

Method of measurement

per liter. per minute

6

Description

level of respiratory support

Timepoint

daily

Method of measurement

severity

Intervention groups

1

Description

Intervention group:reception of fluid 50cc/kg/d

Category

Other

2

Description

Control group:reception of fluid 65 cc/kg/d

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Aiatollah Rohani Hospital

Full name of responsible person

Mitra Gorji Rad

Street address

Ganj afrooz Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Yahyapoor Yoosef

Street address

Babol University of Medical Sciences, Ganjafrooz street

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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, Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mitra Gorji Rad

Position

resident of pediatric

Other areas of specialty/work

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Person responsible for updating data

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Position

resident of pediatric

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

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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