

# 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 fluid 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 مکنونیوم، 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 ، ادرار کمتر از 1سی سی >5 K>20 Bun>150 Na>150 سائیمی، 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 Science  
**Street address**  
Shahid Fahmide Ave,Hamadan Univercity Of Medical Science, 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 respiratory 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 standard 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**

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**Province**

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**Postal code**

651484411

**Phone**

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**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

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**Province**

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**Postal code**

6517789971

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**Email**

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**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

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**Province**

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32640020

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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.

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**Province**

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**Postal code**

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**Phone**

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**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

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Hamedan, Iran.**City**

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**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**

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**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

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**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