

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of chamomilla oil massage versus conventional treatment in bronchiolitis

#### Protocol summary

##### Study aim

the effects of chamomile oil massage in bronchiolitis.

##### Design

This randomized clinical trial was done among bronchiolitis patients with first attack of wheezing which is under 12 months in emergency part of hospital. the researcher called to statistician and she works with PASS11 software and random list and 2 groups contain of 30 sample in case and 30 sample in control group was selected.

##### Settings and conduct

Patient referred to Shahid Sadooghi hospital of Yazd divided by chance number to case and control groups and respiratory score (PRESS) was determined. The primary treatment was begun with Ventolin Nebulizer for both groups with protocol. The case group was massage with the chamomile oil in antero posterior surface of chest by mother every 4 hours( 5 cc for 5 minutes on each side) .The vital signs and PRESS score and any complication were evaluated by the researcher before the massage, one hour later and four hours later and then every 12 hours after the intervention and the control group were evaluated similarly .

##### Participants/Inclusion and exclusion criteria

Inclusion: first wheezing attack in infant under 12 months.  
exclusion: second attack oh wheezing and other major chronic organ disease

##### Intervention groups

massage of chamomile oil for 5 min on both side of chest comparing with control no massage .

##### Main outcome variables

The initial outcomes included changes in the pulse oximetry and oxygen saturation rates, respiratory rate in terms of tachypnea, pulse rate, respiratory sounds, and use of secondary respiratory muscles.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080930001285N1**  
Registration date: **2019-01-10, 1397/10/20**  
Registration timing: **retrospective**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

##### Registration date

2019-01-10, 1397/10/20

##### Registrant information

##### Name

mehrdad shakiba

##### Name of organization / entity

shahid sadooghi hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 151 8475

##### Email address

shakiba@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-09-22, 1395/07/01

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

2016-11-30, 1395/09/10

##### Actual recruitment end date

2018-04-19, 1397/01/30

##### Trial completion date

2018-05-20, 1397/02/30

##### Scientific title

Comparison of chamomilla oil massage versus conventional treatment in bronchiolitis

**Public title**

Effect of chamomille oil massage for bronchiolitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

first attack of bronchiolitis age between 1 to 12 months  
moderate to severe bronchiolitis

**Exclusion criteria:**

prematurity(birth age less than 37 weeks) history of  
bronchiolitis in past chronic heart and lung diseases  
immunodeficiency disease Down syndrome or others  
syndromic disease metabolic or neurological diseases  
The positive history of asthma in the first degree related

**Age**

From **1 month** old to **12 months** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

this randomized clinical trial is done by calling researcher  
to statistic through PASS11 software and random list and  
is designed by simple method and individual unit.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

the local effect of chamomille is tested in treatment of  
bronchiolitis

**Secondary Ids**

empty

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

based on ethics committee of Yazd university of  
medical science

**Street address**

Ebne sina BLV, Shahid Ghandi BLV,

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Approval date**

2018-03-12, 1396/12/21

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1396.266

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

Bronchiolitis

**ICD-10 code**

J21.9

**ICD-10 code description**

Acute bronchiolitis, unspecified

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

Changes in the percentage of venous oxygen saturation  
by pulse oximetry before and after treatment at intervals

**Timepoint**

before and 1 and 4 hour after treatment and then every  
12 hours until discharging of patients.

**Method of measurement**

pulse oximetry divide

**2****Description**

Heart rate changes

**Timepoint**

before and 1 and 4 hour after treatment and then every  
12 hours until discharging of patients.

**Method of measurement**

Awareness of heart rate and counting it in a minute,

**3****Description**

Changes in the number of breaths per minute

**Timepoint**

before and 1 and 4 hour after treatment and then every  
12 hours until discharging of patients.

**Method of measurement**

Listening to the respiratory sound and counting it in a  
minute.

**4****Description**

Change in respiratory sounds

**Timepoint**

before and 1 and 4 hour after treatment and then every  
12 hours until discharging of patients.

**Method of measurement**

The sound of breathing sounds by stethoscope

## 5

### Description

Pediatric Respiratory severity Score

### Timepoint

before and 1 and 4 hour after treatment and then every 12 hours until discharging of patients.

### Method of measurement

Counting numbers

## Secondary outcomes

### 1

#### Description

The secondary outcome was the number of days admitted to the hospital.

#### Timepoint

Until admission in the hospital

#### Method of measurement

counting the days of hospitalization

## Intervention groups

### 1

#### Description

Intervention group: In addition to the treatment of disease by ventolin nebulizer and supportive care (serum and suplimental oxygen therapy) such as control group, chamomile oil massage 5cc for 5 min every 4 hours on anterior and posterior side of chest by mother was administered.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: This group was treated with salbutamol nebulizer and other supportive care ( serum and supplemental oxygen therapy) every 4 hours.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadooghi Hospital

##### Full name of responsible person

Mehrdad Shakiba

##### Street address

Ebne Sina BLV, Shahid Ghandi BLV,

##### City

Yazd

##### Province

Yazd

##### Postal code

8916886938

#### Phone

+98 35 3726 4677

#### Email

shakiba@ssu.ac.ir

#### Web page address

https://www.ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaiee

##### Street address

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd

##### City

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##### Province

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##### Phone

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##### Email

shakiba@ssu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Yazd 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

Yazd University of Medical Sciences

##### Full name of responsible person

Fatemeh Tahghighi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Pediatrics

##### Street address

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid  
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dr.tahghighi@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Mehrdad Shakiba

**Position**

associated professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh Tahghighi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Department of pediatrics, Shahid Sadoughi Hospital ,  
Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd

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**Postal code**

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**Phone**

+98 35 3726 4677

**Email**

dr.tahghighi@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there is no more data.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available