

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 of 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.

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

General information

Reason for update

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 supplimental 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaiee

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

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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

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

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Subspecialist

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Person responsible for updating data

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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