Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 attach 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 reffered 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 sadoghi 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 indivisual 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 divise

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
Street address
Ebne Sina BLV, Shahid Ghandi BLV,
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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
Street address
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
Street address

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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