

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of the effect of *Fumaria parviflora* Lam. aqueous extract versus simethicone on infantile colic

Protocol summary

Study aim

The aim of this prospective, randomized clinical trial was to evaluate the effectiveness, safety and tolerability of *Fumaria parviflora* Lam. (will fumitory) infused aqueous extract on the treatment of infantile colic.

Design

Two arm parallel group randomised trial with blinded postoperative care and blinded outcome assessment

Settings and conduct

49 colicky infants among patients seen at pediatrics department of Khatam Al-Anbia Specialty Clinic were recruited. blinding was applied to patients and statistician

Participants/Inclusion and exclusion criteria

inclusion criteria: 3 to 16 weeks age; cry-fuss behavior that lasted ≥ 3 hours a day for ≥ 3 days in the 1 week before enrollment Exclusion criteria were receiving other drugs for colic treatment and clinical evidence of gastrointestinal disorders or chronic illness

Intervention groups

will fumitory group simethicone group

Main outcome variables

Primary outcome was intervention success; defined as average crying duration decrease to less than 180 minutes/day (according to Wessel's criteria). Secondary outcome was the number of respondents in each group at the end of study. Responding was defined as $\geq 50\%$ reduction in average crying duration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140817018828N5**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **retrospective**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

Alimohammad Ranjbar

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

empty

Scientific title

Study of the effect of *Fumaria parviflora* Lam. aqueous extract versus simethicone on infantile colic

Public title

Effect of will fumitory on infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

3 to 16 weeks age Cry-fuss behavior that lasted ≥ 3 hours a day for ≥ 3 days in the 1 week before enrollment

Exclusion criteria:
Evidence of gastrointestinal disorders or chronic illness
Receiving other drugs for colic treatment

Age
From **21 days** old to **120 days** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**
Actual sample size reached: **49**

Randomization (investigator's opinion)
Randomized

Randomization description
Restricted randomization based on random allocation rule where among 52 patients included, 26 were assigned to receive extract by lot and the remaining were assigned to simethicone group. Randomization was concealed in sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients; Statiscian; The author responsible for gathering data

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yazd University of Medical Sciences

Street address
Ba Honar square

City
Yazd

Province
Yazd

Postal code
8917693571

Approval date
2016-10-16, 1395/07/25

Ethics committee reference number
lr.ssu.medicine.rec.1395.212

Health conditions studied

1

Description of health condition studied
Infantile colic

ICD-10 code
K20-K31

ICD-10 code description
Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description
infant crying duration

Timepoint
before enrollment-day 10 from baseline

Method of measurement
daily diary to assess crying duration

Secondary outcomes

1

Description
number of respondends

Timepoint
day 10 from baseline

Method of measurement
Number of infants who experienced $\geq 50\%$ reduction in average crying duration.

Intervention groups

1

Description
Intervention group: fumitory extract group

Category
Treatment - Drugs

2

Description
Intervention group: simethicone group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam-Al-Anbia multi-specialty clinic

Full name of responsible person

Saeede Ebrahimi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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

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Person responsible for updating data

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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