

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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  $\geq 3$  hours a day for  $\geq 3$  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)

###### Phone

+98 35 3820 3419

###### Email address

amranjbar@razi.tums.ac.ir

##### 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  $\geq 3$  hours a day for  $\geq 3$  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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ShahidTaleghani Blvd  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Hooshang Mehrparvar  
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Bahonar Square, Yazd, Iran  
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ah.mehrparvar@gmail.com  
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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

**Full name of responsible person**  
Alimohamad Ranjbar Jamal abadi  
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Medical Pharmacy  
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## Person responsible for scientific inquiries

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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