Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Stachys Ivandulifolia on primary dysmenorrhea

Protocol summary

Summary
Background: Because of the importance and prevalence of dysmenorrhoea in the world population, (50% of women) this study was conducted to evaluate the therapeutic effects of Stachys Ivandulifolia on primary dysmenorrhoea in women aged 18-25 years. This research is a double-blind randomized clinical trial, that has been done on 50 women aged 18-25 years and 50-60 kg in weight suffering from primary dysmenorrhoea. Intensity of pain was evaluated by Visual Analogue Scale (VAS). Stachys Ivandulifolia was given in traditional method. 10 gram of dried powder of Stachys flowers brewed in hot water given three times a day for 5 days (2 days before up until 3 days after the pain). Then they were followed up for three cycles. Duration and intensity of pain and side effect of drugs was assessed following intervention. Statistical analysis was performed using t-test, chi-square. Key words: primary dysmenorrhoea, Stachys Ivandulifolia, prostaglandins

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT138709051470N1**
Registration date: **2010-05-24, 1389/03/03**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2010-05-24, 1389/03/03

Registrant information
Name
Frozan Ofati
Name of organization / entity
Qazvin University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 28 1333 6498
Email address
folfati@qums.ac.ir

Recruitment status
Recruitment complete
Funding source
Vice chancellor for research Medical University of Qazvin

Expected recruitment start date
2007-04-01, 1386/01/12
Expected recruitment end date
2007-12-30, 1386/10/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Stachys Ivandulifolia on primary dysmenorrhea

Public title
Effect of Toklijeh on menstural pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 50 women in 18-25 years old, 50-60 kg in weight, intensity of pain was 4 and more by visual analogue scale (VAS), duration of pain more than 2 days, with nausea and vomiting, fatigue, headache. Exclusion criteria: secondary dysmenorrhoea
Age
From **18 years** old to **25 years** old
Gender
Female

Phase
2
Groups that have been masked

No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Bahonar Ave.,

City
Qazvin

Postal code
3419759811

Approval date
2006-03-02, 1384/12/11

Ethics committee reference number
28/20/2671

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhoea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Pain duration and severity

Timepoint
After three month

Method of measurement
visoual analogue scale

Secondary outcomes

1

Description
Side effect

Timepoint
after three month

Method of measurement
Questionnaire

Intervention groups

1

Description
Stachys Ivandulifolia was given in traditional method. 10 gram of dried powder of Stachys flowers brewed in hot water given three times a day for 5 days (2 days before up until 3 days after the pain)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Outpatient Clinics of Qazvin University of Medical Sciences

Full name of responsible person
Dr. Asefzadeh

Street address
Qazvin University of Medical Sciences

City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research Medical University of Qazvin

Full name of responsible person
Dr. Saeed Asefzadeh

Street address
Bahonar Ave.,

City
Qazvin

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research Medical University of Qazvin

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Frozan Olfati

Position
Academic member of Nursing and Midwifery school, Qazvin University of Medical Sciences

Other areas of specialty/work

Street address
Bahonar ave

City
Qazvin

Postal code

Phone
+98 28 1223 7268

Fax

Email
folfati@qums.ac.ir; papoy6olfati@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Frozan Olfati

Position
Academic member of Nursing and Midwifery school, Qazvin University of Medical Sciences

Other areas of specialty/work

Street address
Bahonar Ave.,

City
Qazvin

Postal code

Phone
+98 28 1333 6498

Fax

Email
folfati@qums.ac.ir; papoy6olfati@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Frozan Olfati

Position
M.S

Other areas of specialty/work

Street address
Bahonar Ave.,

City
Qazvin

Postal code
3419759811

Phone
+98 912 182 6082

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty