Effect of Stachys Ivandulifolia on primary dysmenorrhoea

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

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 dysmenorrhoea

Public title
Effect of Toklijeh on menstrual 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
Not blinded

Blinding (investigator’s opinion)
Not used

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
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
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Person responsible for updating data

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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