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 dysmenorrhea 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 dysmenorrhea. 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
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Frozan Ofati
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Qazvin University of Medical Sciences
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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 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 dysmenorrhea

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**
    - Visual 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

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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