Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison effect of Fennel/Vitamin E and Ibuprofen on intensity of primary dysmenorrhea at students of Tabriz, 2007-2009.

Protocol summary

Summary

Aim: The purpose of this study was Determine and Comparison the effects of combination extract Fennel and Vitamin E with Ibuprofen on the intensity in primary dysmenorrhoea in the Tabriz city students, 2007-2009. Mateial&Methods: This study was done by double-blinded Quasi Experimental Research method. 68 students from Medical and Tabriz Universities who were living in the dormitory, and suffering from primary dysmenorrhea and had condition of study were separated randomly in two groups (N= 34). Inclusion criteria: primary dysmenorrhea with a sum score of Visual Analogue Scale 3.1- 9, Students with cyclic menstrual bleeding that cycle length between 25 and 35 days and no amenorrheic cycles or cycles without withdrawal bleeding during the last 3 months prior to first visit... Exclusion criteria: Known or suspected NSAIDs allergy or suspected contraindication to herbal remedies... Then the samples recorded Intensity pain of primary dysmenorrhea without medication in the first month; and these groups used "combining extract Fennel and Vitamin E" and Ibuprofen cross-over form in the two mouths. we used VAS tool for defineing the intensity of the pain. Data analyzing was done by using Spss 14 win .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101225664N1**
Registration date: **2011-08-26, 1390/06/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-26, 1390/06/04

Registrant information

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Masoomeh Nasehi
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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2008-12-21, 1387/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Fennel/Vitamin E and Ibuprofen on intensity of primary dysmenorrhea at students of Tabriz, 2007-2009.

Public title

Comparison effect of Fennel/Vitamin E and Ibuprofen on intensity of Primary dysmenorrhea at students of Tabriz, 2007-2009.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy single female students suffering from primary dysmenorrhea with a sum score

of Visual Analogue Scale 3.1 – 9 " students who gained higher than 9.1 (severe dysmenorrhea) and lower than 3 (mild dysmenorrhea) were excluded from survey"; Students with cyclic menstrual bleeding that cycle length between 25 and 35 days and no amenorrheic cycles or cycles without withdrawal bleeding during the last 3 months prior to first visit; Reviewing and Signing of informed consent; The onset of primary dysmenorrhea was before 20 years. Exclusion criteria: Severe pain in all of menstruation period or before onset of cycling bleeding; Known or suspected NSAIDs allergy or suspected contraindication to herbal remedies; Using of Oral Hormonal Contraception during treatment; History of pelvic major surgery; Presence or a history of seizure; severe gastrointestinal disorders or any diseases that might interfere with the conduct of the study or the interpretation of the results; Urinary tract infection in study period; Simultaneous participation in another clinical trial or participation in another clinical trial prior to study entry that might have an impact on the study objectives at the discretion of the investigator; Using of tranquilizer or any non medical treatment for dysmenorrhea pain relief.

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical, Golgasht street, Tabriz, Iran.

City
Tabriz

Postal code
5165665931

Approval date
2008-10-26, 1387/08/05

Ethics committee reference number
8731

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhoea

ICD-10 code
N94.4 Pr

ICD-10 code description
N94 Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
Intensity of the pain of Primary dysmenorrhoea

Timepoint
Hours 1,2,3,6,12,24,48 after onset of bleeding

Method of measurement
Subjects recorded intensity of menstrual pain by Visual Analogue Scale(0-10)

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description
Cap 500 mg (60 mg Fennel extract / 150 UI Vitamin E) QID N=1 at first two day of menstration

Category
Treatment - Drugs

2

Description
Cap Ibuprofen 400 mg QID N=1 at first two day of menstration
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar dormitory
Full name of responsible person
Masoomeh Nasehi
Street address
Kosar dormitory, Finally South Shariati street, Tabriz, East Azarbayejan, Iran.
City
Tabriz

2

Recruitment center
Name of recruitment center
Fajr dormitory
Full name of responsible person
Masoomeh Nasehi
Street address
Fajr dormitory, Rah Ahan Street next to the Seventh Tir hospital, Tabriz, East Azarbayejan, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Reza Ostadrahimi
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Tabriz University of Medical Sciences Research, Golgagsht Street, Tabriz, East Azarbayejan, Iran.
City
Tabriz
Grant name
10506
Grant code / Reference number
124202
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
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
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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