Clinical Trial Protocol
Iranian Registry of Clinical Trials
02 May 2019

Effect of ginger and novafen on menstrual pain: A cross-over clinical trial

Protocol summary

Study aim
The aim of this randomized, double blind cross-over clinical trial is to investigate an alternate herbal treatment for dysmenorrhea. In this study, 168 patients with dysmenorrhea who meet the inclusion/exclusion criteria will be recruited and randomly assigned into the two following groups. The patients will be assigned into two groups (ginger and novafen) in a cross over way with similar form and dosage. Intensity of dysmenorrhea will be measured by using visual analog scale (VAS) and compared between groups.

Design
cross-over clinical trial study.

Settings and conduct
Cross-over and Babol University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Students of Babol University of Medical Sciences. The inclusion criteria included: age of 18 to 26 years, regular period, menstrual pain in the first three days of menstruation, primary dysmenorrhea grade 2 and grade 3. The exclusion criteria included: secondary dysmenorrhea, mild dysmenorrhea (grade 1), using pain relief medication and hormonal medications, no proper use of medicine, failure to record pain intensity, heavy exercises, kidney / liver disease and pelvic operation, severe stress, serious family arguments and experiencing severe stress during 6 months before the study.

Intervention groups
The intervention group 1 received 200 mg of Novafen capsule made by al-Hawi Company in the first 2 days of the first menstrual cycle every 6 hours (4 capsules per day) and 200 mg of Ginger capsule made by Barij Company during the first 2 days of the second menstrual cycle every 6 hours (4 capsules per day). The washout period was 28 days. The intervention group 2 received 200 mg of Ginger capsule made by Barij Company in the first 2 days of the first menstrual cycle every 6 hours (4 capsules per day) and 200 mg of Novafen capsule made by al-Hawi Company during the first 2 days of the second menstrual cycle every 6 hours (4 capsules per day). The washout period was 28 days.

Main outcome variables
Reduction of dysmenorrhea.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT201108285683N2
Registration date: 2011-09-17, 1390/06/26
Registration timing: prospective

Last update: 2018-03-14, 1396/12/23
Update count: 1

Registration date
2011-09-17, 1390/06/26

Registrant information
Name
Hajar salmalian
Name of organization / entity
Babol University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Babol University of Medical Sciences- Goldaru company

Expected recruitment start date
2011-10-08, 1390/07/16

Expected recruitment end date
2015-04-19, 1394/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of ginger and novafen on menstrual pain: A cross-over clinical trial

Public title
An alternate herbal treatment for dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
- single girl students 18 to 26 years old
- high school with no history of abdominal or pelvic surgery or any specific disease who were suffering from primary dysmenorrhea, grade 2 or 3.

Exclusion criteria:
- improper administration of the medication, administration of contraceptive pills or another medication whilst on research, history of allergies to Ginger, severe stress, heavy exercise.

Age
- From 18 years old to 26 years old

Gender
- Female

Phase
- 2

Groups that have been masked
- Participant
- Investigator

Sample size
- Target sample size: 168

Randomization (investigator's opinion)
- Randomized

Randomization description
- Random numbers

Blinding (investigator's opinion)
- Double blinded

Blinding description
- In this study, both Novafen and Ginger were replaced in 200 mg capsules of the same shape and color. Participants and researcher did not know the type of capsules.

Placebo
- Not used

Assignment
- Crossover

Other design features

Secondary Ids
- empty

Ethics committees

1

Ethics committee
- Name of ethics committee: Medical Ethics Committee of Babol University of Medical Sciences
- Street address: Babol University of Medical Sciences, Ganj Afrooz Avenue
- City: Babol
- Province: Mazandaran
- Country: Iran (Islamic Republic of)
- Postal code: 4717647745

Approval date
- 2011-08-13, 1390/05/22

Ethics committee reference number
- 4419

Health conditions studied

1

Description of health condition studied
- dysmenorrhea

ICD-10 code
- 094-099

ICD-10 code description
- Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description
- Primary dysmenorrhea

Timepoint
- Prior to the intervention, 2 months after the initiation of intervention (2 first days of 2 subsequent cycles)

Method of measurement
- Visual analogue scale (VAS), Verbal Multidimensional scoring system, COX -Table

Secondary outcomes
- empty

Intervention groups

1

Description
- Intervention group Includes students who received 200 mg Ginger capsules (orally every 6 hours) in the first two days of the first cycle, 200 mg Novafen capsules (orally every 6 hours) in the first two days of the second cycle.

Category
- Treatment - Drugs

2

Description
- Control group Includes students who received 200 mg Novafen capsules (orally every 6 hours) in the first two days of the first cycle, 200 mg Ginger capsules (orally every 6 hours) in the first two days of the second cycle.

Category
- Treatment - Drugs

Recruitment centers
Recruitment center
Name of recruitment center
Babol University of Medical Sciences
Full name of responsible person
Hajar Adib Rad- Reproductive Health, PhD( Faculty Member)
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Sponsors / Funding sources
1
Sponsor
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Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Zahra Basirat
Position
Obstetrics & Gynecologist/ Faculty member
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data is available in Babil University of Medical Sciences.
When the data will become available and for how long
At any time.
To whom data/document is available
Everybody
Under which criteria data/document could be used
In order to treat and under any circumstances.
From where data/document is obtainable
Researcher and Babil University of Medical Sciences.
What processes are involved for a request to access data/document
Corresponding with the researcher.
Comments