**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

**Country**  
Iran (Islamic Republic of)

**Phone**  
+98 112199595

**Email address**  
h.salmalian@mubabol.ac.ir

**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**
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
Medical Ethics Committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganj Afroz 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
dysmenorrheal

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)

Street address
Babol-ghanj afrooz Ave-Babol University of Medical Sciences, Babol, Iran.

City
Babol

Province
Mazandaran

Country
Iran (Islamic Republic of)

Postal code
4717647745

Phone
+98 11 3219 9595

Email
adibrad2015@yahoo.com

Sponsors / Funding sources

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Amrolah Mostafazadeh

Street address
Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Country
Iran (Islamic Republic of)

Postal code
4717647745

Phone
+98 11 3219 9595

Email
adibrad2015@yahoo.com

Grant name

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

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Babol University of Medical Sciences, Babol

City
Babol

Province
Mazandaran

Country
Iran (Islamic Republic of)

Postal code
4717647745

Phone
+98 11 1219 9595

Fax
Email
basiratzahra@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Hajar Adib Rad

Position
Reproductive Health, PhD- Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Country
Iran (Islamic Republic of)

Postal code
4717647745

Phone
+98 11 3219 9595

Fax
Email
Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Hajar Adib Rad
Position
Reproductive Health, PhD - Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Babol University of Medical Sciences
City
Babol
Province
Mazandaran
Country
Iran (Islamic Republic of)
Postal code
4717647745
Phone
+98 11132199595
Fax
Email
adibrad@yahoo.com
Web page address

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
Researchers at Babil University of Medical Sciences.

What processes are involved for a request to access data/document
Corresponding with the researcher.

Comments