Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Dec 2019

Evaluation of the Effect of Administration of Lactobacilli on Pain Relief in Endometriosis

Protocol summary

Study aim
Evaluate the effect of Lactobasili on reducing the pain associated with endometriosis

Design
In this pragmatic, community based, parallel group, triple-blind, randomisd controlled trial, 30 patients with endometriosis referring to Rasoul-e-Akram Hospital who are eligible for entering the study are enrolled. Patients are randomly allocated into two groups: intervention and control groups; and each participant will be assigned a code.

Settings and conduct
In this clinical trial study, all patients who underwent laparoscopic surgery in Rasool Akram Hospital and have proven endometriosis make the study population. Then, the patients enter the study according to the inclusion and exclusion criteria and after getting written consent. This study is designed triple-blind (patients, interventionist, analyst) , and only an observer will be informed of the groupings.

Participants/Inclusion and exclusion criteria
Major Inclusion Criteria: 1) Definitive diagnosis of endometriosis; 2)Menstrual cycle in the range of 21-35 days; 3) Aged 18-45 years; 4) Those who had VAS Score intensity of 5 or more for their pain intensity; 5) Passing at least 3 months and 1 year at the most since surgery Major Exclusion Criteria: 1) Patients who had received hormonal treatment during the past 3 months; 2) History of liver or renal disease; 3) history of carcinoma; 4) Patients with history of diarrhea after consuming dairy products; 5) Consumption of food or any type of probiotic product; 6) Those who had a pain intensity of less than 5 according to the VAS Score.

Intervention groups
Group 1: Placebo treatment: 1 palcebo tablets daily as a control group Group 2: Daily treatment of once daily lactobasili tablets

Main outcome variables
severity of dysmenorrhea severity of chronic pelvic pain severity of dyspareunia total VAS score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150819023684N5**
Registration date: **2018-04-17, 1397/01/28**
Registration timing: **retrospective**

Last update: **2018-04-17, 1397/01/28**
Update count: **0**

Registration date
2018-04-17, 1397/01/28

Registrant information

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Sepideh Khodaverdi

Name of organization / entity
Iran University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research, Iran University of Medical Sciences (Primary sponsor) Zist Takhmir Pharmaceutical Company

Expected recruitment start date
2016-11-21, 1395/09/01

Expected recruitment end date
2017-11-22, 1396/09/01

Actual recruitment start date
2016-12-10, 1395/09/20

Actual recruitment end date
2017-09-21, 1396/06/30

Trial completion date
empty

Scientific title
Evaluation of the Effect of Administration of Lactobacilli on Pain Relief in Endometriosis

Public title
Evaluation of the Effect of Lactobacilli on Pain Relief in

Endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of endometriosis Menstrual cycle in the range of 21-35 days Aged 18-45 years Those who had VAS (Visual Analogue Scale) Score intensity of 5 or more for their pain intensity Passing at least 3 months and 1 year at the most since surgery

Exclusion criteria:

Patients who had received hormonal treatment during the past 3 months History of liver or renal disease history of carcinoma Patients with history of diarrhea after consuming dairy products Consumption of food or any type of probiotic product Those who had a pain intensity of less than 5 according to the VAS Score Patients who had received antibiotics during the past 3 months

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple random method was used for Randomization with using random numbers table. for allocations concealment, individuals outside the study were used for random allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is designed triple -blind, so that the researcher, subject and statistical analyst are not aware of the status of the allocation of the two groups. Because the administration of the drug and placebo happens under the exactly same appearance, therefore, the subject is not aware of the assignment of the groups. The researcher measuring clinical and diagnostic measures is not aware of the status of the individual, and the statistician is also unaware of the allocation of people to study groups. Only the observer is aware of the allocation of the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran, Iran

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Tehran

Province

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1445613131

Approval date

2016-12-04, 1395/09/14

Ethics committee reference number

IR.IUMS.REC 1395.9311290013

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Mean VAS score

Timepoint

8 and 12 weeks after starting of drug use

Method of measurement

VAS Questionnaire

Secondary outcomes

1

Description

Drug Adverse Effects

Timepoint

8 and 12 Weeks after starting drug use

Method of measurement

Questionnaire

Intervention groups

1

Description
Intervention Group: Lactobacilli tablets, once daily with the trade name "Lactofem" from Zist Takhmir Pharmaceutical Company which contains 10 to the power 9 colony count of the following lactobacilli: Lactobacillus acidophilus, Lactobacillus plantarum, Lactobacillus fermentum, Lactobacillus gasseri. The tablet will be taken for 8 weeks and the patient will be evaluated after 8 and 12 weeks after the beginning of the treatment.
Category
Treatment - Drugs

2

Description
Control group: Placebo treatment; daily 1 tablet of the placebo which is made by the pharmaceutical company Zist Takhmir with the exactly same packaging and appearance with "Lactofem". The tablet will be taken for 8 weeks and the patient will be evaluated after 8 and 12 weeks after the beginning of the treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul- E - Akram Hospital
Full name of responsible person
Dr. Sepideh Khodaverdi
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr. Sepideh Khodaverdi
Position
Assistant Professor, Fellowship in Minimally Invasive Gynecologic Surgery
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not 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
All data except personal information

When the data will become available and for how long
After publication of Paper

To whom data/document is available
Researchers working in research and academic centers

Under which criteria data/document could be used
further research

From where data/document is obtainable
Dr. Khodaverdi

What processes are involved for a request to access data/document
Request via email

Comments