

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 Lactobacilli on reducing the pain associated with endometriosis

Design

In this pragmatic, community based, parallel group, triple-blind, randomised 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 placebo tablets daily as a control group
Group 2: Daily treatment of once daily lactobacilli 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

Name

Sepideh Khodaverdi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2562

Email address

khodaverdi.s@iums.ac.ir

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

City

Tehran

Province

Tehran

Postal code

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

Street address

Rasoul- E - Akram Hospital, Niayesh Avenue, Sattarkhan Street, Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2562

Email

sepidehkhodaverdi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Malakooti

Street address

Vice Chancellor for Research, Iran University of

Medical Sciences, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

adminsitem@iums.ac.ir

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

Street address

Rasool Akram Hospital, Niayesh St. Sattarkhan Street. Rasool Akram Hospital, Department of Obstetrics and Gynecology, Endometriosis Research Center.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2562

Fax

Email

sepidehkhodaverdi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran university of medical science

Full name of responsible person

Dr. Sepideh Khodaverdi

Position

Assistant professor, Fellowship in Minimally Invasive
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Latest degree

Specialist

Other areas of specialty/work

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Street address

Rasool Akram Hospital, Niayesh Avenue, Sattarkhan
Street.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2562

Fax

Email

sepidehkhodaverdi@yahoo.com

Web page address

Rasool Akram Hospital, Department of Obstetrics and
Gynecology, Endometriosis Research Center

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2562

Fax

Email

sepidehkhodaverdi@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

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

Person responsible for updating data

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

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