

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the effect of Palm pollen regimen with Letrozole and Tamoxifen in treatment of infertile women in Jahrom City

Protocol summary

Study aim

Comparison of the effect of Palm pollen regimen with Letrozole and Tamoxifen in treatment of infertile women in Jahrom City

Design

Randomized clinical trial with parallel groups

Settings and conduct

In this study, patients with infertility who referred to Jahrom clinic during three months were randomly divided into two groups: control and Intervention. In Intervention group take herbal diet Palm pollen 120mg/kg as 500 mg capsules. The control group will receive regular treatment of infertility including letrozole and tamoxifen (Tamoxifen tab 10mg Bid and Letrozol 2.5 mg Bid). Finally, on the eighth day of the menstrual cycle, vaginal sonography will be performed to evaluate the effects of drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women who had no pregnancy history after 12 months of unprotected intercourse
Exit criteria: Women with endometriosis

Intervention groups

Intervention group: herbal diet Palm pollen 120mg/kg as 500 mg capsules. control group: Tamoxifen tab 10mg Bid and Letrozol 2.5 mg Bid from 3th days of menstruation

Main outcome variables

The frequency of pregnancy after each treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150407021653N16**
Registration date: **2019-01-18, 1397/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

Registration date

2019-01-18, 1397/10/28

Registrant information

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 5432 6602

Email address

a.rasekh@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2019-05-22, 1398/03/01

Trial completion date

empty

Scientific title

Comparison of the effect of Palm pollen regimen with Letrozole and Tamoxifen in treatment of infertile women in Jahrom City

Public title

Comparison of the effect of Palm pollen regimen with Letrozole and Tamoxifen in treatment of infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women who had no pregnancy history after 12 months of unprotected intercourse

Exclusion criteria:

Women with endometriosis

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **128**

Actual sample size reached: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jahrom University of Medical Sciences

Street address

Jahrom, Motahari Blvd. Pardis building

City

Jahrom

Province

Fars

Postal code

7414846199

Approval date

2018-08-05, 1397/05/14

Ethics committee reference number

IR.JUMS.REC.1397.03514

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Determine the frequency of pregnancy after each treatment

Timepoint

2 years

Method of measurement

Based on the β -HCG test

Secondary outcomes

1

Description

The average thickness of the endometrium before and after treatment

Timepoint

On the eighth day of the menstrual cycle

Method of measurement

Vaginal Sonogarchy

2

Description

Frequency of ovarian follicles count before and after treatment

Timepoint

On the eighth day of the menstrual cycle

Method of measurement

Vaginal Sonogarchy

Intervention groups

1

Description

Intervention group: herbal diet Palm pollen 120mg/kg as 500 mg capsules with citresin anti-allergic acid tablets of 10 mg every 8 hours to prevent the onset of allergy from the first day of menstruation.

Category

Treatment - Drugs

2

Description

control group:Tamoxifen tab 10mg Bid and Letrozol 2.5 mg Bid from 3th days of menstruation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Rasekh Infertility Clinic

Full name of responsible person

Athar Rasekh Jahromi

Street address

Jahrom Avenue 22 Bahman Dr. Rasekh Infertility Clinic

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a.rasekh@jums.ac.ir

Jahrom University of Medical Sciences

Full name of responsible person

Athar Rasekh Jahromi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Pardis building, Motahari Blvd., Jahrom

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Athar Rasekh Jahromi

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Jahrom, street 22 Bahman, opposite the governorate

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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

Jahrom 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Athar Rasekh Jahromi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

Jahrom University of Medical Sciences

Full name of responsible person

Pardis Abtahian

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available