Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of the effectiveness of vitamin C supplementation with balance diet, versus Placebo on the Luteinizing hormone, follicle-stimulating hormone, Dehydroepiandrosterone, testosterone, estradiol, progesterone and sex hormone-binding protein in infertile women with polycystic ovary syndrome

Protocol summary

Summary

This double-blind crossover randomized trial is a study foe measuring the effectiveness of vitamin c supplementation on several hormones levels in infertile women with a balanced diet. Inclusion Criteria: Having 2 of 3 criteria Rotterdam; Women with at least one year before entering the study had tried unsuccessfully to conceive; women aged 35-18 years and exclusion criteria: Unwillingness to continue working; sensitivity to vitamin c; abnormal bleeding .In this study, 56 infertile women with polycystic ovarian syndrome entered the study.The 56 women were divided into two groups of 28 And every menstrual cycle hormone test groups on day 3 (estradiol, Dehydroepiandrosterone, testosterone, sex hormone-binding protein, Luteinizing hormone, follicular hormone) and then one group received placebo and the other group vitamin C for one month, and then day 22 menstrual cycle is done progesterone test. Medication is discontinued and was done repeated on day 3 of menstruation hormone testing and control groups changed in the intervening months, the intervention group as in the control group.On 22 trial done, and the drug was discontinued in subsequent periods last 3 days of testing done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013030312672N1**
Registration date: **2013-04-22, 1392/02/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-04-22, 1392/02/02

Registrant information

Name
Razeieh Hosseini

Name of organization / entity
The Ministry Of Health, Shiraz University Of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 711235782

Email address
hoseiniraz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effectiveness of vitamin C supplementation with balance diet, versus Placebo on the Luteinizing hormone, follicle-stimulating hormone,

Dehydroepiandrosterone, testosterone, estradiol, progesterone and sex hormone-binding protein in infertile women with polycystic ovary syndrome

Public title
The effect vitamin C supplementation on infertile women with polycystic ovary syndrome
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: People who are willing to cooperate; Having 2 of 3 criteria Rotterdam; Women with at least one year before entering the study had tried unsuccessfully to conceive; women aged 35-18 years; Do not use alcohol; Not used hormonal drugs within the last 2 months; No abnormal bleeding; Women who still have a normal uterus and tubal; Normal Spermogram man; Disorders related to reproductive hormones; no history of pelvic surgery; The absence of Laparoscopic Surgery; Body Mass Index between 19/8 to 29 exclusion criteria: Unwillingness to continue working; sensitivity to vitamin c; abnormal bleeding.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Shiraz University Of Medical Of Research , Ministry of Health
Street address
Research Deputy, Shiraz University of Medical Science
City
Shiraz
Postal code
Approval date
2012-06-14, 1391/03/25
Ethics committee reference number
CT-91-6086

Health conditions studied

1

Description of health condition studied
Infertility, polycystic ovarian disease
ICD-10 code
N.97
ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
LH
Timepoint
Day 3 of the first menstruation, second cycle Day 3, Day 3 of the third period
Method of measurement
ELIZA

2

Description
FSH
Timepoint
Day 3 of the first menstruation, second cycle Day 3, Day 3 of the third period
Method of measurement
ELIZA

3

Description
DHEAS
Timepoint
Day 3 of the first menstruation, second cycle Day 3, Day 3 of the third period
Method of measurement
ELIZA

4

Description
Testosterone
Timepoint
Day 3 of the first menstruation, second cycle Day 3, Day 3 of the third period
Method of measurement
ELIZA

5

Description
Estradiol

Timepoint
Day 3 of the first menstruation, second cycle Day 3, Day 3 of the third period
Method of measurement
ELIZA

6

Description
progesteone
Timepoint
Day 22 of first cycle, Day 22 of the second cycle
Method of measurement
ELIZA

7

Description
SHBG
Timepoint
Day 3 of the first menstruation, second cycle Day 3, Day 3 of the third period
Method of measurement
ELIZA

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group in the early period of hormone tests performed and then 750 mg of vitamin C per day prescribed treatment period lasted up to 22 days and then tested progesterone medication is discontinued. In the next cycle day 3 hormonal tests done again, this time as the 22 day period will receive a placebo control group.
Category
Treatment - Drugs

2

Description
The control group in the early period of hormone tests performed and then placebo prescribed treatment period lasted up to 22 days and then tested progesterone medication is discontinued. In the next cycle day 3 hormonal tests done again, this time as the 22 day period will receive a 750 mg of vitamin C Intervention group .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
The Mother and Child Hospital (Ghadir)
Full name of responsible person
Razieh Hosseini
Street address
Quran Gate, Shiraz
City
Shiraz

2

Recruitment center
Name of recruitment center
Motahari Clinic
Full name of responsible person
Razieh Hosseini
Street address
Zand Street, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
Gholamreza Hatam
Street address
Technology and Research Office, Research Deputy , Shiraz University of Medical Science, Zand Street, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University Of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz College Of Nursing Midwifery
Full name of responsible person
Sadigheh Forouhari
Position

Master Of Midwifery, Guide Master
Other areas of specialty/work
Street address
College Of Nursing Midwifery, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1242 4128
Fax
Email
Forouharism@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz College Of Nursing Midwifery
Full name of responsible person
Sadigheh Forouhari
Position
Master of Midwifery , Guide Master
Other areas of specialty/work
Street address
College Of Nursing Midwifery, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1242 4128
Fax
Email
Forouharism@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz College Of Nursing Midwifery
Full name of responsible person
Sadighe Forouhari
Position
Master Of Midwifery, Guide Master
Other areas of specialty/work
Street address
College Of Nursing Midwifery, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1235 7282
Fax
+98 71 1230 7594
Email
Forouharism@yahoo.com
Web page address
www.Sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty