

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of Tonic Onsoli syrup and Samgh capsule on creat of the Menstrual cycle in women with Polycystic Ovary Syndrome (PCO) in a pilot study.

Protocol summary

Study aim

Our aim in this study was to investigate the effect of traditional medicine (Tonic Onsoli syrup and Samgh Capsule) on monthly bleeding in patients with Polycystic Ovary Syndrome and oligomenorrhea.

Design

Clinical trials with single group, study type: before and after, simple random sampling and sample size: 20 patients were enrolled in the study. Phase II clinical trial

Settings and conduct

Patients with Polycystic Ovary Syndrome referring to the Gynecology Clinic of School of Traditional Medicine, Shahid Beheshti Medical Sciences How to do the study: before and after

Participants/Inclusion and exclusion criteria

"Inclusion criteria": Women (married and single) with Polycystic Ovary Syndrome with major complaint of Oligomenorrhea; Age of 17-45 years "Exclusion Criteria": The presence of any systemic disease with Hyperinsulinaemia and Hyperandrogenism; Pregnancy, Abortion or Postpartum within 6 weeks; Taking hormone medications in the last month; Family history of Breast and Ovarian cancer; Patients who are planning to have pregnancy

Intervention groups

People with Polycystic Ovary Syndrome and oligomenorrhea who receive the product of traditional medicine (Tonic Onsoli syrup and Samgh Capsule)

Main outcome variables

Occurrence of menstruation, BMI, waist circumference, abdominal circumference, Body fat mass

General information

Reason for update

Acronym

PCOS

IRCT registration information

IRCT registration number: **IRCT20180217038764N1**

Registration date: **2019-06-12, 1398/03/22**

Registration timing: **retrospective**

Last update: **2019-06-12, 1398/03/22**

Update count: **0**

Registration date

2019-06-12, 1398/03/22

Registrant information

Name

Mojgan Tansaz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3525

Email address

tansaz_mojgan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-12, 1397/02/22

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Tonic Onsoli syrup and Samgh capsule on creat of the Menstrual cycle in women with Polycystic Ovary Syndrome (PCO) in a pilot study.

Public title

Tonic Onsoli in Polycystic Ovary

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women (married and single) suffering from PCOS with the main complaint of Oligomenorrhea Age of 45-17 years Patient Satisfaction

Exclusion criteria:

The presence of any systemic disease with Hyperinsulinaemia and Hyperandrogenism Pregnancy, abortion or postpartum in the last 6 weeks Breastfeeding in the first 6 months Use of hormonal medications in a recent month Patients who are planning to have a pregnancy.

Age

From **17 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

No 30. Shams Ave, Opposite Tavanir, Valiasr Street

City

Tehran

Province

Tehran

Postal code

1516745811

Approval date

2017-01-29, 1395/11/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.901

Health conditions studied

1

Description of health condition studied

Polycystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Women's menstruation

Timepoint

Before starting the study and 1 month after entering the plan and at the end of the study

Method of measurement

Ultrasound and hormonal testing

Secondary outcomes

1

Description

Oligomenorrhea bleeding

Timepoint

Before starting the study and 1 month after entering the plan and at the end of the study

Method of measurement

Ultrasound and hormonal testing

Intervention groups

1

Description

At night, a capsule of 250 mg with warm water is applied, Components of the drug: Bindaj, Isha, Ishq, Gum (Barley) (2 units); Jundabidder (1 unit); Hanzal (2/5 units); Vinegar (to the required amount).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Medicine Clinic of Shahid Beheshti University

Full name of responsible person

Mojgan Tansaz

Street address

NO.30, Shams Alley, Vali-e Asr Ave, Tehran, Iran

City

Tehran

Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Email
tansaz_mojgan@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Somayeh Esmaeili
Street address
NO.30, Shams Alley, Vali-e Asr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Email
sesmaeili@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mojgan Tansaz
Position
Assistant Professor, Faculty of Traditional Medicine,
Shahid Beheshti University
Latest degree
Ph.D.
Other areas of specialty/work

Traditional Medicine

Street address

No. 30, Shams Alley, Vali-e Asr Ave, Tehran, Iran

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Province

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1516745811

Phone

+98 21 8877 3521

Email

tansaz_mojgan@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mojgan Tansaz
Position
Assistant Professor, Faculty of Traditional Medicine,
Shahid Beheshti University
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
NO.30, Shams Alley, Vali-e Asr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Email
tansaz_mojgan@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mojgan tansaz
Position
Assistant Professor, Faculty of Traditional Medicine,
Shahid Beheshti University
Latest degree
Specialist
Other areas of specialty/work
Traditional Medicine
Street address
No. 30, Shams Alley, Vali-e Asr Ave, Tehran, Iran
City
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Province
Tehran

Postal code
1516745811
Phone
+98 21 8877 3521
Email
tansaz_mojgan@sbmu.ac.ir

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

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

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The questionnaires used and the information about the main outcome after the 3 months of publication of the results are shared with the applicants.

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

Researchers working in institutions academic and scientific

Under which criteria data/document could be used

Students doing thesis Research centers

From where data/document is obtainable

Mojgan Tansaz tansaz_mojgan@yahoo.com Tel: 02188773525

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

After 6 months of sampling and 2 months of statistical analysis and 3 months after printing results It takes about 14 months to complete. Information is provided to the applicant.

Comments