Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The effect of Liraglutide on clinical and paraclinical symptoms in patients with polycystic ovary syndrome with high body mass index in patients referred to Shahrekord endocrinology clinics

Protocol summary

Study aim

Determining the effect of liraglutide on clinical and paraclinical symptoms in patients with polycystic ovary syndrome with high body mass index in patients referred to Shahrekord endocrinology clinics.

Design

This study is clinical trial, phase 2 which will be carried out on 35 reffering patient with polycystic ovaries with a body mass index above 25 kg/m2.

Settings and conduct

35 patients with polycystic ovary syndrome with high body mass index referred to Shahrekord endocrinological clinics, liraglutide was prescribed for three months and its effect on their clinical and paraclinical symptoms was investigated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with polycystic ovary syndrome between the ages of 18 and 45 years, giving written and oral consent to participate in the study, and not having chronic physical diseases (except for polycystic ovary syndrome) and mental diseases or long-term use of drugs according to the patient, index Body mass more than 25 kg/m2.Exclusion criteria: Smoking, suffering from other causes of hyperandrogenism such as congenital adrenal hyperplasia, Cushing's syndrome, ovarian or adrenal tumor, pregnancy, menopause, taking medications that lead to side effects such as menstrual disorders, hirsutism, or acne, and medications that affect the lipid profile or blood sugar during the last 3 months such as OCP, thiazides, hydrocortison, metformin and the like, history of previous pancreatitis and family history of medullary thyroid carcinoma (mtc)

Intervention groups

Liraglutide treated group

Main outcome variables

weight before and after the study; hair loss before and after the study; menses before and after the study; hirsutism before and after the study; Acne before and after the study; lipids before and after the study; fasting insulin before and after the study; Fasting blood sugar before and after the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220720055510N1**
Registration date: **2022-07-30, 1401/05/08**
Registration timing: **prospective**

Last update: **2022-07-30, 1401/05/08**
Update count: **0**

Registration date

2022-07-30, 1401/05/08

Registrant information

Name

Fariba Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3338 3448

Email address

mansouri.fa@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-08, 1401/05/17

Expected recruitment end date

2022-10-09, 1401/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Liraglutide on clinical and paraclinical symptoms in patients with polycystic ovary syndrome with high body mass index in patients referred to Shahrekord endocrinology clinics

Public title

The effect of Liraglutide on clinical and paraclinical symptoms in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with polycystic ovary syndrome between the ages of 18 and 45 years, Written and oral consent is obtained from patients to participate in the study Do not have chronic physical diseases (except polycystic ovary syndrome) and mental diseases. According to the patient, there is no long-term use of drugs. Body mass index is more than 25 kg/m2.

Exclusion criteria:

Smoke. suffering from other causes of hyperandrogenism such as congenital adrenal hyperplasia, Cushing's syndrome, ovarian or adrenal tumor. Taking drugs that lead to side effects such as menstrual disorders, hirsutism or acne, or affect the profile of fat or blood sugar in the last 3 months, such as OCP, thiazides, corten, metformin, etc. be pregnant. Menopause Have a history of previous pancreatitis. Have a family history of medullary thyroid carcinoma (mtc).

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **35**

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 shahrekord University of Medical Sciences

Street address

shahrekord University of Medical Sciences, kashani Blvd.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2022-06-14, 1401/03/24

Ethics committee reference number

IR.SKUMS.REC.1401.056

Health conditions studied

1

Description of health condition studied

Poly cystic ovary syndrom

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Fasting insulin

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Laboratory

2

Description

Fasting blood glucose

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Laboratory

3

Description

Menstruation

Timepoint

Before the intervention and three months after the intervention

Method of measurement
Patient History

4

Description
hirsutism
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Ferriman-Gallwey scoring system, observation

5

Description
Acne
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Observation

6

Description
TG,HDL,LDL
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Laboratory

7

Description
Weight
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Scale

8

Description
hair loss
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Patient history

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with polycystic ovary syndrome with high body mass index referred to Shahrekord endocrinology clinics who are treated with liraglutide drug under the brand name Victoza from Novonordisk pharmaceutical company. Liraglutide drug is used subcutaneously at a dose of 0.6 mg in the first week, 1.2 mg in the second week, and then 1.8 mg in the third week until the end of three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Specialized Clinic
Full name of responsible person
Mahboube taghipour
Street address
Shariati Blvd., Imam Ali Specialized Clinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Zahra Habibi dastenaei
Street address
Vice-Chancellor's Office for Research, Shahr-e-Kord University of Medical Sciences, Kashani Ave.
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Chahar-Mahal-va-Bakhtiari
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Phone
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Email
habibi.z@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Fariba mansouri

Position
Internal medicine resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Internal medicine group office, Hajar hospital, Parastar Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Mahboube taghipour

Position
Associate professor

Latest degree
Subspecialist

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Person responsible for updating data

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Phone
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Email
Dr.f.mansouri.1393@gmail.com

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