A pilot study to test the PCOS risk algorithm (PriskA)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Observational invasive

Summary

ID

NL-OMON53945

Source
ToetsingOnline

Brief title
PriskA pilot study

Condition

- Endocrine disorders of gonadal function

Synonym
PCOS, Polycystic ovary syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Roche Diagnostics AG,Roche Riagnostics International AG

Intervention

Keyword: Algorithm, PCOS

Outcome measures

Primary outcome

The validity of the PriskA tool to diagnose PCOS, by assessing the sensitivity and specificity of the risk probabilities of 0.2 and 0.8. Parameters that will be used:

- Testosterone level in serum (using Elecsys using Cobas 6000)
- SHBG level in serum (using Elecsys using Cobas 6000).
- AMH level in serum (using Elecsys using Cobas 6000).
- LH level in serum (using Elecsys using Cobas 6000)
- FSH level in serum (using Elecsys using Cobas 6000)
- Cycle information
- Age
- BMI

Secondary outcome

A secondary study parameter is to assess the number (percentage) and characteristics of patients with a PriskA score between 0.2-0.8.

Characteristics will include: menstrual cycle information, age, BMI, serum LH, serum FSH, serum AMH, serum testosterone, serum SHBG, serum progesterone, serum estradiol, total follicle count, PCOS phenotype (if applicable), WHO diagnosis or other endocrinological diagnosis.

Another secondary parameter is the user experience of the PriskA tool. This

will be collected from every user by a questionnaire. Questionnaires will be

collected from every user when he/she completed 20 patients during the study.

Study description

Background summary

With a prevalence up to 15%, polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women of reproductive age. Women with PCOS present with diverse features, including reproductive features such as irregular menstrual cycles, subfertility, hirsutism and pregnancy complications, metabolic features such as obesity, insulin resistance, metabolic syndrome, pre-diabetes, type 2 diabetes and cardiovascular factors, and psychological features such as anxiety and depression (2-5). Because of the reproductive, metabolic and cardiovascular risk factors it is important to screen and inform these women. However, up to 70% of the affected women remain undiagnosed (7). In academic hospitals (tertiary care) the diagnosis PCOS will rarely be missed by gynecologists. However, in peripheral hospitals or for internal medicine physicians, PCOS and its criteria are less well known.
Therefore, the PCOS risk algorithm (PriskA), a digital tool to use in the assessment of PCOS in patients with signs and symptoms of PCOS, is developed. To exclude patients with a WHO I status, the tool exclude women with low Luteinizing Hormone (LH) and low Follicle-Stimulating Hormone (FSH) in advance. Women with LH and FSH within the normal range will be used in the algorithm for further assessment. The algorithm uses clinical data including age, BMI and information about irregular menstrual cycle in combination with anti-Mullerian hormone (AMH), testosterone and Sex Hormone Binding Globulin (SHBG) to generate a risk score ranging from 0-1. Women having a risk score below 0.2 are considered having a low risk of having PCOS, women with a risk score 0.2-0.8 are considered having a moderate risk of having PCOS and women with a risk score above 0.8 have a high risk of having PCOS.

Study objective

In this study we aim to assess the validity of the PriskA algorithm to diagnose PCOS in a pilot study with patients presenting with signs and symptoms of PCOS. The study also aims to collect information on the user experience from the clinicians and to provide useful information to support the design of a validation study.

Study design

This study will be a prospective, mono-center observational pilot study and it

will be conducted at the Department of Reproductive Endocrinology at the Erasmus University Medical Center Rotterdam, the Netherlands. We estimate that the study will be completed within one year.

Study burden and risks

Burden associated with participation is the withdrawal of one extra blood sample during the standardized blood withdrawal that is part of the standardized screening. Participating in the study will not influence the final diagnosis or the follow-up of clinical care. There are no risks for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Women with signs and symptoms of PCOS, including: irregular or absent menstrual cycle, hirsutism or polycystic ovarian morphology who undergoing a standardized screening (COLA screening)
- Age range 16-45 years
- Sufficient command of the Dutch language
- Signed written informed consent

Exclusion criteria

- Documented ongoing pregnancy
- Malignancy (documented malignancy, documentation of current radiation therapy or chemotherapy in medical record)
- If transvaginal ultrasound is not possible or it is inappropriate
- Not willing to share clinical data with Roche and Evidencio
- Use of hormonal medication in the past three months, including hormonal IUD

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2023
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	14-02-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82155.078.22