Pergoveris patients’ profile and outcome response measurement in IVF/ICSI autologous cycles (PERFORM)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000435

Study ID

1000000435

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy

- [ ] Norway
- [ ] Romania
- [ ] Spain
- [ ] Switzerland

Study description

This study is a multi-center and multi-country, prospective, observational study.
The primary objective is to describe patients' profiles for whom r-hFSH/r-hLH combination (Pergoveris) is administered in a real-world clinical setting, where treatment with ART is provided as part of routine care.
The secondary objective is to describe the OS protocols and to evaluate the outcomes of OS and IVF/ICSI cycle in patients for whom r-hFSH/r-hLH combination (Pergoveris) is given in a real-world clinical setting, where treatment with ART is provided as part of routine care

The study will include approximately 1,500 participants undergoing OS cycles with Pergoveris who consent to participate.
The study will be conducted in approximately 37 study centers across Germany, Spain, Italy, France, Switzerland, Greece, Romania, and Norway.
As this is a non-interventional study, the decision to treat patients with Pergoveris is at the discretion of the attending physician and is independent from participation in this study.
Treatment with Pergoveris should be discussed prior to and independent of discussion of study participation. Participants will be recruited for approximately 22 months. Each participant will be followed until a pregnancy test is carried out, OS failure, treatment discontinuation, or withdrawal from the study.
In case of a positive pregnancy test, each participant will be followed until a pregnancy outcome (e.g. miscarriage, termination, or live birth) occurs.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

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Institution

Contact details

Study institution contact

Merck KGaA service@merckgroup.com

Study contact

service@merckgroup.com

Primary lead investigator

Prof. Dr. med. Stefan Kissler

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/06/2024

Actual: 03/06/2024

Study start date
Planned: 20/08/2024

Actual: 20/08/2024

Data analysis start date
Planned: 29/10/2027

Date of final study report
Planned: 15/03/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Healthcare KGaA

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

MS200061_0073

Methodological aspects

Study topic:

Human medicinal product

Study type:

Non-interventional study

Study design:

This study is a multi-center and multi-country, prospective, observational study aimed at characterizing the patient population undergoing OS with Pergoveris in autologous IVF/ICSI cycles, along with assessing the outcomes of this stimulation protocol.

Main study objective:

To describe patients’ profiles for whom r-hFSH/r-hLH combination (Pergoveris) is administered in a real-world clinical setting, where treatment with ART is provided as part of routine care

Study Design

Non-interventional study design

Other

Non-interventional study design, other

A multi-center and multi-country, prospective, observational study.

Study drug and medical condition

Medicinal product name

PERGOVERIS

Medicinal product name, other

follitropin alfa / lutropin alfa

Population studied

Short description of the study population

The study population will be identified according to the inclusion and exclusion criteria below. Participants are only eligible to participate in the study for 1 OS cycle.

Participants are eligible to be included in the study only if they meet all the following criteria:

1. Age 18-45 (inclusive) years at consent
2. 1st, 2nd, or 3rd OS cycle for ART treatment
3. AMH levels available in the 6 months prior to signing of ICF
4. Use of Pergoveris (r-hFSH:r-hLH 2:1) from Day 1 of the OS cycle
5. Plan to use of GnRH analog to prevent premature LH surge
6. Plan to use of luteal phase support with progesterone supplementation (oral, vaginal, and/or intramuscular)
7. Stimulation started after date of local EC approval

Special population of interest

Women of childbearing potential not using contraception

Estimated number of subjects

1500

Study design details

Outcomes

Baseline characteristics

• Age

• Male partner age

• Ethnicity

• Race

• Height

• Weight

• BMI

• Lifestyle factors

• Medical history

• Comorbidities

• Infertility diagnosis

• Duration of infertility

• 1st, 2nd, or 3rd OS cycle for ART treatment

• Baseline hormone analysis

• Reproductive history

• AMH levels in the previous 6 months

• AFC data in previous 6 months, as available

• AFC data for current OS cycle, as available

• Male partner spermiogram in previous 6 months, as available

• Previous OS cycle for IVF/ICSI and outcome information (if applicable)

Data analysis plan

No hypothesis will be tested in the study. Descriptive statistics will be presented as such:

• For continuous variables: case count, mean, SD, mode, minimum and maximum values, median and first quartile (Q1) – third quartile (Q3).

Descriptive results will be reported with appropriate decimal places (e.g. mean will be reported to the same decimal place as raw data and SD will be reported

with 1 more decimal place than mean). The presence and number of missing data will be reported, and descriptive statistics will be calculated from the values provided (i.e. non-missing values) only. Furthermore, for a visual description, histograms will be used to describe the distribution of the variables.
• Categorical variables will be summarized using counts and percentages. The modality “missing data” will be considered as a possible level, with its size and its proportion calculated relative to the total number of study participants at the corresponding time frame, if not specified differently. Percentages of the other modalities will be calculated relative to the total (i.e. non-missing plus missing). Descriptive results for means (i.e. for continuous variables) will be reported with appropriate decimal places (e.g. mean will be reported to the same decimal place as raw data and SD will be reported with 1 more decimal place than mean).

In addition, event rates (with 95% CI) will be estimated per initiated cycle, OPU, and embryo transfer. Abortion rate and ectopic pregnancy rate will be estimated per 100 clinical pregnancies.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

An eCRF will be used to collect data from patients’ medical records in this study

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

CDISC SDTM

CDM website

https://www.cdisc.org/standards/foundational/sdtm

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No

Procedures

Procedure of data extraction

https://na4.medrio.com/MedrioWeb/app/analyze/DataExport.aspx