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Fertility window study in subfertile patients with a desire to learn more about female fertility

Submission date
28/07/2025

Recruitment status
No longer recruiting

Registration date
10/09/2025

Overall study status
Completed

Last Edited
26/01/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There isn't much research on when subfertile women (those who have trouble getting pregnant) are most likely to conceive. Scientists can estimate the fertile window (the days when pregnancy is most likely) by looking at hormone levels and changes in the body, especially in the cervix. Changes can be tracked using different tools, including hormone tests and ultrasound. One key sign is a rise in luteinizing hormone (LH), and other types of biomarkers for detecting the fertile window, which helps trigger ovulation. By studying these signs, doctors can better understand fertility in women who are struggling to conceive. Research shows that different types of cervical mucus come from specific areas of the cervix. This helps doctors track how mucus changes during the fertile window. These insights can improve the chances of pregnancy, especially for women with certain medical conditions. Checking cervical mucus has become a useful and low-cost way to help identify the best time to try for a baby. One method involves looking at the structure of the mucus to see if it forms channels that help sperm swim.
This study focuses on a specific pattern in cervical mucus called P-type crystallization, which may appear during the most fertile days. The goal is to show how this pattern can be used as a simple, affordable tool to help identify peak fertility.

Who can participate?
Women who are having trouble getting pregnant and are being treated using NaProTechnology and Restorative Reproductive Medicine (RRM) methods.

What does the study involve?
The study looked at women during their fertile window to see how well they were ovulating and whether their cervical mucus showed the P-type crystallization pattern. Researchers used computer analysis to study the mucus samples and compared them to see if the pattern could be reliably identified. One expert reviewed the samples, and the study also tracked whether the women became pregnant.

What are the possible benefits and risks of participating?
The only discomfort was from collecting the mucus sample, and no complications were reported.

There were no risks involved.
The study aimed to create a reliable test to check the quality of cervical mucus using its crystallization pattern. This method helps pinpoint the most fertile days and could be especially useful when combined with other tests like liquid biopsies. It may offer a new option for women who want to better understand their fertility. The study also opens the door for future tools that could help assess fertility more accurately. Since this is a new approach, the results are compared carefully with other studies. This personalized method could be helpful for those using RRM, which focuses on restoring natural fertility. In summary, combining mucus quality, correct timing, and the P-type pattern could significantly boost the chances of getting pregnant.

Where is the study run from?
Clinical Consulting G&E (Spain)

When is the study starting and how long is it expected to run for?
December 2021 1 to February 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
José María Murcia Lora, clinicalconsultinggye@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

PI-548

Study information

Scientific Title
Assessment of the fertile window in subfertile patients using the P-type crystallization biomarker in liquid endocervical biopsy: a prospective study

Study objectives
The working hypothesis of the study is to evaluate the contribution of determining type P crystallisation in cervical secretions, together with the evaluation of the fertile window in subfertile patients, as an aid in detecting the moment of greatest fertility.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/12/2021, Ethics Committee for Research La Rioja Clinic (CEICLAR) (C/Piqueras 98, Logroño La Rioja, 26006, Spain; +34 (0)941278855; secretaria.ceic@riojasalud.es), ref: CEImLAR PI-548

Study design
Prospective observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Infertility

Interventions
A prospective study was conducted between February 2022 and February 2023 on 45 subfertile patients who had undergone an infertility study in which the NaProTechnology and the RRM approaches were considered. The implemented strategy, based on NaProTechnology protocols, was to specify the observation and coding of cervical mucus examination during the fertile window, and to use the definition of the peak day of the fertile window according to CrMS. Sterility was defined as the inability of a couple to achieve pregnancy. Infertility was defined as the inability to achieve pregnancy with the birth of a newborn, and subfertility as any form of reduced fertility, broadly defined as the inability to have a pregnancy after regular unprotected sex for 12 months. In women aged 35 years or older, the definition of subfertility is typically 6 rather than 12 months of unprotected sex. To ensure the accuracy of the test and the identification pattern, a statistical study was carried out to validate the identification pattern of the P-type crystallization. For this purpose, a computer analysis of the crystallization pattern of a P-type secretion was undertaken. Subsequently, this tool was used as a comparison method between two sets of digitized cervical-secretion-crystallisation samples to validate its

application. The comparison of the P-type crystallization patterns was performed by a single person with experience in fertility awareness. Finally, six patients were randomly selected from the study group to assess the final outcome of the pregnancy.

Intervention Type
Other

Primary outcome(s)
Hexagonal crystallization pattern type P, measured using endocervical liquid biopsies collected within the fertile window from 3 days before the Peak Day (P Day) until P Day, which is the last day with fertile mucus according to CrMS

Key secondary outcome(s))
The final pregnancy outcome is determined by recording a positive urine HCG pregnancy in the patient's medical history, or by confirmation by the patient that she has become pregnant

Completion date
01/02/2023

Eligibility

Key inclusion criteria
1. Women who wished to be treated using NaPro-Technology and an RRM approach
2. Functional gynecological pathologies that could affect follicular development were considered for treatment, such as hypothyroidism, hirsutism, hyperandrogenemia, luteal-phase defects, delayed maturation of follicular development, polycystic ovary syndrome (PCOS) and other causes such as stress, hyperprolactinemia, or pre-obesity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
42 years

Sex
Female

Total final enrolment
18

Key exclusion criteria

1. Patients who required surgery to resolve an infertility problem
2. Any pathology that required more time to resolve, such as premature ovarian failure, azoospermia, hyperprolactinemia secondary to pituitary microadenomas
3. Patients with hyperthyroidism, obesity, or anorexia
4. Pathologies requiring further intervention, either surgical or prolonged medical intervention
5. Myomatous uterus requiring surgical intervention or hyperplasia

Date of first enrolment
01/02/2022

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
Spain

Study participating centre
Clinicalconsulting G&E
C/Vara de Rey 42, 2º C - D
Logroño La Rioja
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Sponsor information

Organisation
Clinical Consulting G&E

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets used and analyzed during the present study are available upon reasonable request and describing the reason to the corresponding author.
The main contact is José María Murcia Lora (clinicalconsultinggye@gmail.com).
The data that can be shared upon request are the digital images of the P-type crystallization assessment.
The relevant clinical data that can be shared are those related to the final subgroup of patients with a final outcome. These data will be published in Table 1 and Table 2 of the article, which will be published and can be consulted when viewing the published article without prior request.
The availability date will be from the moment the article is published, which will occur as soon as this process is completed, with a 99% probability by September 2025 at the latest.
In accordance with the Organic Law on Data Protection (LOPD) of 13 December 1999 on the protection of personal data, the personal data provided will not be disclosed to third parties and its custody and security are guaranteed by our information systems and internal working procedures. The information provided has been collected to support and develop clinical and research work. The direct relationship between volunteers is intended to provide accurate information and to develop and process the material collected.
All data collected is kept anonymous.
There are no ethical restrictions. Only the inclusion and exclusion criteria were taken into account in the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/09/2025	26/01/2026	Yes	No