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Evaluation of the accuracy of Inito Fertility Monitor

Submission date	Recruitment status	[_] Prospectively registered
05/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/12/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/06/2023	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
The Inito Fertility Monitor is intended to be used for the measurement of hormone levels in urine samples. The system is intended for home use by people or point-of-care (POC) use by a trained health care professional as an aid in the diagnosis of infertility. The aim of this clinical study is to evaluate the performance of the Inito Fertility Monitor in the measurement of three key fertility hormones: luteinizing hormone (LH), estradiol glucuronide (E3G), and pregnanediol glucuronide (PdG) using urine samples.
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Who can participate?
Adult women aged between 21 and 45 years of age with an average menstrual cycle length of 21 to 42 days.

What does the study involve?
Clinical performance of the Inito Fertility Monitor will be compared to two other methods for measuring hormone levels: the Clearblue Fertility Monitor and a laboratory investigation called ELISA.

Participants will collect urine samples at home every day for the duration of one menstrual cycle (the time from the first day of their period to the day before their next period) and these will be tested with Inito Fertility Monitor and Clearblue Fertility Monitor. Inito Fertility test strips and Clearblue test strips were dipped in the samples for 15 sec and after 5 min, readings from the respective devices were recorded. The samples for assessment with ELISA will be also collected from the users and transported to the investigational centre in dry ice within 30 min of collection.

What are the possible benefits and risks of participating?
Around 45-50% of women are unaware of their fertile window. The fertile window may vary depending on various factors such as age, lifestyle, or genetic predisposition. Previously it has been shown that estrone-3-glucuronide (E3G) and luteinizing hormone (LH) can be used to identify the fertile window. Also, anovulatory cycles occur in around 37-42% of natural cycles. Therefore, the confirmation of ovulation is sought after by both clinicians and patients and an additional measurement of pregnanediol-3-glucuronide (PdG) can be used to confirm ovulation.

By taking part in this study, participants can identify their fertile window and hormone concentrations throughout the cycle, if their hormone fluctuations are as expected or do the hormones behave abnormally, and if their menstrual cycles are ovulatory or anovulatory.

No risks have been identified as being associated with taking part in this trial.

Where is the study run from?
Sparsh Hospital (India)

When is the study starting and how long is it expected to run for?
From June 2019 to December 2019

Who is funding the study?
Inito (India)

Who is the main contact?
Mr Siddharth Pattnaik,
siddharth@inito.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
U85110KA2003PTC032782

Study information

Scientific Title
Validation of Inito Fertility Monitor with respect to laboratory measures of fertility related hormones

Study objectives
The Inito Fertility Monitor can measure concentrations of urinary hormones estradiol glucuronide, luteinizing hormone, and pregnanediol glucuronide with laboratory-grade accuracy and can predict the fertile days in women accurately

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2019, Sparsh Hospital Institutional Ethics Committee (146, Infantry Road, Opposite to Police Commissioner's Office, Bengaluru 560001; +91-80-61222000; enquiry@sparshhospital.com), ref: CLIN/INI/001

Study design
Single-centre observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Home

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Female infertility

Interventions
Urine samples were collected by each participant at home every day for the duration of one menstrual cycle. The samples were frozen by putting the samples in the cold box container provided and sent to the testing site. The box provided contained a temperature logger in order to ensure that the temperature is maintained during transport to the testing site. The testing was done at the Inito laboratory situated at Bionest, IKP Eden, 16, Bhuvanappa Layout, Tavarekere Main Rd, Bengaluru, 560029.

Urine samples were tested with both the Inito Fertility Monitor and Clearblue Fertility Monitor using test strips for the respective devices. Inito Fertility test strips and Clearblue test strips were dipped in the samples for 15 sec, and, after 5 min, readings from the respective devices were recorded.

Each volunteer was assigned a unique ID. 3 participants were randomly selected and samples over the course of 1 cycle for each of these participants were collected for comparison of Inito and enzyme-linked immunosorbent assay (ELISA). The samples were collected from the participants and transported to the investigational centre in dry ice within 30 min of collection. The samples were aliquoted into 2 ml tubes and stored at -20°C in order to preserve the concentration of all the hormones.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Inito Fertility Monitor

Primary outcome measure
1. Device readings of luteinizing hormone (LH), estradiol glucuronide (E3G), and pregnanediol glucuronide (PdG) measured using the Inito Fertility Monitor, Clearblue Fertility Monitor, and ELISA with urine samples collected daily for the course of 1 menstrual cycle

Secondary outcome measures

1. User feedback on the sufficiency of data measured using a questionnaire at the end of 1 menstrual cycle
2. Lifestyle or infertility related conditions measured using an onboarding questionnaire at baseline

Overall study start date
15/03/2019

Completion date
06/12/2019

Eligibility

Key inclusion criteria
1. Women aged between 21 and 45 years
2. Menstruation cycle length of 21 to 42 days
3. Willing to provide written informed consent to participate in the study and comply with the investigational procedures

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
100

Total final enrolment
177

Key exclusion criteria
1. Have a condition that is known to be contra-indicated in pregnancy
2. Using or have used in their last 2 cycles, hormonal contraceptives, including oral, emergency oral, implants, patches, transdermal injections, vaginal ring, or progesterone intrauterine systems (IUS)
3. Using or have used in the last 2 cycles, infertility medications or hormone replacement therapy containing luteinizing hormone (LH) or human chorionic gonadotropin (hCG)
4. Taking clomiphene citrate or other ovulation induction drugs
5. Are using any treatment which may affect the menstrual cycle
6. Have recently been pregnant, miscarried, or breastfeeding
7. Have been diagnosed with polycystic ovarian syndrome (PCOS)

Date of first enrolment
06/06/2019

Date of final enrolment
06/11/2019

Locations

Countries of recruitment
India

Study participating centre
Sparsh Hospital
146 Infantry Road
Opposite to Police Commissioner's Office
Bengaluru
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Sponsor information

Organisation
Inito

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Sponsor type
Industry

Website
http://www.inito.com

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
The datasets generated will be available upon request from Siddharth Pattnaik (siddharth@inito.com). The datasets generated contain:
1. For the comparison between ELISA and Inito Fertility Monitor (IFM), the re-predicted concentration obtained from ELISA and IFM and the correlation plots between ELISA and IFM for predicting estrone-3-glucuronide (E3G), luteinizing hormone (LH), and pregnanediol-3-glucuronide (PdG) concentrations.
2. Fertility ratings obtained from Clearblue Easy Fertility Monitor and Inito Fertility Monitor for each participant on all days of the menstrual cycle.
3. Graphs of hormone fluctuations during menstrual cycles of all the participants obtained using the Inito Fertility Monitor acquired on the Inito application.
The data generated from the study is available anytime. All data generated and analyses are proprietary to Inito and will be made available for reference only. The data cannot be used as raw data for any other analysis or publication, unless already published by Inito or unless permitted by Inito. Consent from all participants has been obtained in order to use the data for publication. The participants' names have been anonymised during their inclusion in the study itself. Data pertinent to the trials (including BMI, average cycle length, lifestyle, and whether participants are trying to conceive or not) have been collected and can be made available along with the analysis as well.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		12/05/2021	14/03/2022	No	No
Other publications	Results from a technology verification cohort of blood samples collected from 20 new users of the Inito Fertility Monitor following the same protocol as the primary cohort	21/12/2022	23/01/2023	Yes	No
Results article		07/06/2023	08/06/2023	Yes	No