Analysis of human uterine temperature and pH and uterine fluid composition

Published: 09-05-2023
Last updated: 19-08-2024

The main objective of this study is to measure the human uterine temperature and pH and to analyze the composition of aspirated uterine fluid of 30 women of reproductive age from a Dutch population three or four days after ovulation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON54424

Source
ToetsingOnline

Brief title
Human uterine characteristics

Condition

- Other condition

Synonym
Uterus characteristics

Health condition

baarmoederomstandigheden en IVF behandeling

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: een studiebeurs van het Amsterdam Reproduction & Development research institute

Intervention

Keyword: Fluid composition, pH, Temperature, Uterus

Outcome measures

Primary outcome

Primary study outcomes will be the mean (SD) temperature and the mean (SD) pH measured in the uterine cavity of women from a Dutch population at the time of the menstrual cycle an embryo normally implants, and the average concentration (mean ± SEM) of at least thirty-seven components present in fluid aspirated from the uteri of the same women at the same time.

Secondary outcome

The difference between the primary results and previous results from the uteri of Iranian women and the difference between the primary results and the current human embryo culture conditions for human IVF, determined with an independent T-test (temperature and pH) or one-way ANOVA (uterine fluid components).

Study description

Background summary

In vitro fertilization (IVF) has revolutionized reproductive medicine.
Currently around 2 million IVF treatments are provided worldwide each year.
However, only about one third of all treatments started results in live birth.
There is a strong incentive to optimize embryo culture conditions in order to improve IVF efficacy. In the development and optimization of embryo culture conditions in human IVF the use of mouse embryos have been playing a dominant

role. Limited research has been performed on the human in vivo environment of preimplantation embryos, leaving substantial gaps in our knowledge of the optimal conditions for human embryo development. Therefore, new studies elucidating the natural environment of human preimplantation embryos in vivo are urgently needed to enable mimicking of the natural environment in vitro. It is expected that this will improve human embryo quality and subsequently IVF efficacy (higher pregnancy rates) and safety (the health of IVF children).
Our research group previously measured physiological conditions - temperature and pH - in the uterus of 53 Iranian women during the implantation window, i.e. the window of the menstrual cycle in which implantation of the embryo would normally take place, and analyzed 22 uterine fluid samples on the presence and concentration of 37 components. This resulted in clear clues on how to improve IVF culture conditions. However, additional research is required to confirm these results in women from a different population and thereby exclude (epi)genetic and/or nutritional effects on uterine characteristics.

Study objective

The main objective of this study is to measure the human uterine temperature and pH and to analyze the composition of aspirated uterine fluid of 30 women of reproductive age from a Dutch population three or four days after ovulation.

Study design

Observational study.

Participants will monitor their ovulation with a urine dipstick LH-test and pay an extra visit to the Center of Reproductive Medicine at Amsterdam UMC, location AMC for the uterine measurements. Three or four days after ovulation the temperature and pH will be measured in the uterine cavity with a temperature probe and a pH catheter through an outer cathether. Also uterine fluid will be aspirated at that time and later analysed on the presence of at least thirty-seven components. Results will be compared with previous results obtained from a different population of Iranian women and also with the embryo culture conditions currently used in human IVF. This study will thereby demonstrate whether there is a difference in uterine characteristics between women with different (epi)genetic and nutritional backgrounds. With the knowledge from these studies we will then improve current human embryo culture conditions.

Study burden and risks

The risk and burden on the subjects in this study are considered to be minimal. Participants will make an additional visit to the hospital for uterine measurements and uterine fluid aspiration. From our previous study in which the same procedures were performed, we know that the risk of side effects is

negligible. In addition, a risk inventory has been carried out. It is possible that participants will experience discomfort from uterine contractions after the procedure, which is comparable to the possible discomfort after an embryo transfer. There is no direct benefit from this study to the participants in this study. After participating in this study, participants will receive standard fertility treatment. The results of this study are solely for scientific enrichment and will be substantial in our understanding of the natural embryonic environment in humans and will be used to optimize the current human embryo culture system used in general in clinical IVF.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Reproductive age (18-43 years old)
Regular menstrual cycle

Normal transvaginal ultrasound
Planned ICSI treatment due to (severe) male factor subfertility or planned fertility treatment with donor sperm
Written informed consent

Exclusion criteria

Unexplained subfertility, tubal infertility or premature ovarian failure
The presence of untreated unilateral or bilateral hydrosalpinx
A history of dilatation and curettage
Previous caesarean section with niche formation
Malformation of the urogenital system
Endometriosis
Untreated/unsubstituted endocrine abnormalities (e.g. pituitary, thyroid, adrenal or pancreas abnormalities).
PCOS

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-07-2023
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	09-05-2023

Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	13-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL76759.018.22