Home-based monitoring of ovulation to time frozen embryo transfer in IVF.

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Assessing (cost-)effectiveness of home based monitoring with urinary LH tests (true natural cycle frozen embryo transfer, true NC-FET) versus hospital controlled monitoring with repeated ultrasound monitoring and hCG trigger (modified NC-FET) to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON55569

Source
ToetsingOnline

Brief title
Antarctica 2 study

Condition

- Sexual function and fertility disorders

Synonym
frozen embryo transfer (FET) in the natural cycle (ovulation)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW doelmatigheid;reeds toegepaste interventies

Intervention

Keyword: frozen thawed embryo transfer, in vitro fertilization, medically assisted reproduction, modified natural cycle, true natural cycle

Outcome measures

Primary outcome

Ongoing pregnancy per woman after a single FET cycle.

Secondary outcome

Cancellation rates, patient satisfaction (anxiety, contentedness, feeling of

empowerment, discretion), partner participation, miscarriage rates, Live birth

rates, costs

Study description

Background summary

Frozen-thawed embryo transfer (FET) is at the heart of modern IVF and has been made possible by -ongoing- improvements in laboratory techniques for freezing and thawing of embryos (1).The number of FET cycles is increased substantially over the past decade (Dutch national
IVF results, NVOG 2015 (2)). Currently, 37% of children born from IVF/ICSI treatments is the result of the transfer of a frozen-thawed embryo in the Netherlands (www.nvog.nl). It is to be expected that the relative contribution of FET to the cumulative ongoing pregnancy rates will further increase.

For FET to be effective, the endometrium needs to be synchronized with the developmental stage of the embryo to allow implantation. There are two methods to do so: embryo transfer in the natural cycle (NC-FET) with repeated ultrasound monitoring of the dominant follicle followed by hCG trigger or embryo transfer in an artificial cycle (AC-FET) with estrogen and progesterone tablets. A recently performed multicentre non inferiority trial (NTR1586, ANTARCTICA TRIAL,), conducted within the Dutch Consortium for Healthcare Evaluation and Research in Obstetrics and Gynecology, demonstrated that NC-FET was non-inferior to AC-FET in live birth rates. The economic analysis showed that NC-FET is the dominant strategy. NC-FET is therefore to be preferred over AC-FET (4).

During a NC FET cycle the woman has to visit the hospital for ultrasound monitoring on average three times (unpublished data ANTARTCICA TRIAL). From the woman*s point of view a more natural approach and less interference with private and working life is desired (5). Home based monitoring in fresh IVF cycles indeed improved patient-reported outcomes such as contentedness, empowerment, discretion and partner participation (6). Therefore, home based monitoring might be also be the preferred treatment for women in FET cycles.

An alternative to the previously described NC-FET which implies hospital controlled monitoring, is true natural cycle FET (true NC-FET) in which the natural ovulation is monitored using urinary LH tests. This allows women to monitor their natural ovulation at home, reducing direct costs - of repeated ultrasound visits and medication - and indirect costs - of transportation to the clinic and productivity loss-. Because of this advantages, true NC FET is increasingly being applied in the Netherlands, albeit in the absence of evidence supporting its (cost-)effectiveness.

Study objective

Assessing (cost-)effectiveness of home based monitoring with urinary LH tests (true natural cycle frozen embryo transfer, true NC-FET) versus hospital controlled monitoring with repeated ultrasound monitoring and hCG trigger (modified NC-FET) to time frozen embryo transfer in IVF.

Study design

Multicentre, non-inferiority RCT with a cost-effectiveness analysis.

Intervention

INTERVENTION: True natural cycle FET with home-based monitoring of ovulation with urinary LH tests

USUAL CARE /COMPARISON: Modified NC-FET with repeated ultrasound monitoring of the dominant follicle followed by hCG trigger.

Study burden and risks

As we compare strategies that are already current practices, no additional risks or burdens are expected from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women that have undergone IVF/ICSI who are scheduled for frozen embryo transfers.

Exclusion criteria

anovulation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2018
Enrollment:	1464
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2018
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2020
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-06-2021
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	NL62924.018.17
Other	NTR 27578