ANTARCTICA trial: Cryo-thawed embryo transfer: natural versus artificial cycle. A non inferiority trial.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25356

Source
Nationaal Trial Register

Brief title
ANTARCTICA trial

Health condition

EN: subfertility, cryo thawed embryo transfer, IVF
NL: subfertiliteit, gecryopreserveerder embryo's, IVF

Sponsors and support

Primary sponsor: Isala Klinieken
dr. BJ Cohlen & drs. ER Groenewoud
Postbus 10400
8000 GK Zwolle
Source(s) of monetary or material Support: Stichting Fertiliteitsafdeling.

Intervention

Outcome measures

Primary outcome

Live birth rate.

Secondary outcome

1. Clinical pregnancy, ongoing pregnancy, cancellation rates (per started cryo cycle).

2. Endometrial growth.

3. Cost efficiancy and analyses of the burden of treatment.

4. SAE.

Study description

Background summary

Cryopreservation of embryos derived from IVF or IVF-ICSI treatment is a save and cost efficient supplement to regular IVF treatment. Before transferring the embryo’s into the uterus it’s necessary to synchronise development of embryo and endometrium. This synchronisation is essential for the success of the treatment. Because of this need cryo embryo transfer needs planning en preparation. The are several methods of endometrial preparation preceding frozen thawed embryo transfer. Most common are natural cycle and artificial cycle preparation. Both are accepted methods of endometrium preparation and it’s common opinion that live birth rates are comparable. Despite this claim so far no randomised study has been undertaken to confirm this statement.

Study objective

To compare live birth rates among patients receiving cryo thawed embryo transfer after endometrial preparation with estrogen/progesterone substitution and patients receiving cryo thawed embryo transfer in a natural cycle.

Study design

No interim analysis will be performed. Total duration of the study will be 3 years (+ 9 months follow up of pregnant subjects).

Intervention

Cryo thawed embryo transfer in natural cycle versus artificial cycle.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients between 18 en 40, planning to receive a frozen thawed embryo transfer, embryos orginated out of IVF/ICSI treatment 1,2 or 3.

2. Patients are willing to participate during 1 frozen thawed embryo transfer treatment cycle and are willing to sign informed consent.

3. Ovulatoir menstruationcycle between 26 and 35 days.

Exclusion criteria

Patients with a contraindication for medication used in this study such as:

1. Trombo-embolic event in the patients history;

2. Severe disorder of liverfunction;

3. Estrogen sensitive tumors;

4. Breastcancer;

5. Porfyria;

6. Patients with a known allergy for one of the used medicines;

7. Patients with anovulatory menstruation cycles;

8. Patients with uterine abnormalities;

9. Patients with cryo embryos derrived from oocyte donation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	1150
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1515
NTR-old	NTR1586
Other	ABR/eudraCT : 23273/2008-002689-68
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results