A multi-center double-blind randomized controlled trial of two media for the in vitro culture of human preimplantation embryos.

No registrations found.

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

Summary

ID

NL-OMON24976

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Subfertility; Infertility

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Primary outcome measure will be live birth rate per patient after one year of treatment.

Secondary outcome

Secondary outcome measures will be embryo quality, clinical pregnancy rate, ongoing pregnancy rate, miscarriage rate, time to pregnancy, birth weight and percentage of children with congenital abnormalities.

Study description

Background summary

This study investigates whether the use of G5-medium for the in vitro culture of human preimplantation embryos leads to an improved live birth rate per patient as compared to the use of HTF-medium.

Study objective

To investigate whether the use of G5-medium for the in vitro culture of human preimplantation embryos leads to an improved live birth rate per patient as compared to the use of HTF-medium.

Study design

The duration of the study is three years.

Intervention

Ovarian hyperstimulation, oocyte retrieval and oocyte fertilization will be performed using standard procedures. In the experimental arm, all oocytes and resulting embryos will be cultured in G5-medium and in the control arm, oocytes and resulting embryos will be cultured in HTF-medium.

Contacts

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Eligibility criteria

Inclusion criteria

Subfertile couples undergoing IVF (in vitro fertilization) or ICSI (intracytoplasmatic sperm injection).

Exclusion criteria

1. Couples undergoing a PGD cycle;

2. Couples for which IVF is used to prevent the transmission of HIV;

3. Couples undergoing a modified natural cycle.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2009
Enrollment:	784
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	NL1866
NTR-old	NTR1979
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A