Comparing IVF results when using two commercially available culture media - a multi-center randomized controlled trial

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To compare two widely used IVF culture media (G5 and HTF) to find out which one leads to the best live birth rate per patient.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32460

Source
ToetsingOnline

Brief title
Medium-trial

Condition

- Other condition

Synonym
subfertility

Health condition

subfertiliteit

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: culture medium, in vitro fertilization, randomized controlled trial

Outcome measures

Primary outcome

Primary outcome measure will be the percentage of live births after one year of treatment.

Secondary outcome

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

Study description

Background summary

A variety of culture media for human preimplantation embryos are currently used in human in vitro fertilization procedures (IVF). Previous studies have indicated that alterations in the composition of the culture media could affect embryo quality and pregnancy rates. Despite the importance of culture media, it is not known what is the best medium to use for human in vitro fertilization procedures.

Study objective

To compare two widely used IVF culture media (G5 and HTF) to find out which one leads to the best live birth rate per patient.

Study design

A multi-center, randomized, double-blinded comparison of G5 and HTF for human

preimplantation embryo culture.

Intervention

Ovarian hyperstimulation and oocyte retrieval will be performed using standard procedures. In the experimental arm, all oocytes and resulting embryos will be cultured in G5-medium in all treatments for the duration of one year after randomisation and in the control arm, oocytes and resulting embryos will be cultured in HTF-medium in all treatments for the duration of one year after randomisation. Embryo selection and transfer will subsequently be performed using standard procedures.

Study burden and risks

After providing written consent, there is no involvement, burden or benefit for the participating women. These women follow normal routine IVF procedures. The only difference between both arms of the study is the culture medium used. Both media are certified and have been used extensively both in the Netherlands and abroad without any complications.

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

All couples that present to one of the participating centers for their first, or first after a successful pregnancy, IVF/ICSI treatment.

Exclusion criteria

Couples undergoing a PGD cycle, couples for which IVF is used to prevent the transmission of HIV and couples undergoing a modified natural cycle will be excluded.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2010
Enrollment:	784
Type:	Actual

Ethics review

Approved WMO Date:	12-04-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-05-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-07-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-09-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL30441.000.09
Other	NTR1979 (Dutch Trialregister ID)