Comparing IVF results when using two commercially available culture media (part 2) - a multi-centre randomized controlled trial

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To compare two internationally widely used IVF culture media, the sequential culture medium G5 (G1.5 for culture on day 1-3 and G2.5 for day 4-6) from Vitrolife (Sweden) and a single step Continuous Single Culture Medium (CSCM) from Irvine (Ireland...

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

Summary

ID

NL-OMON47201

Source
ToetsingOnline

Brief title
MEDIUM2

Condition

- Other condition

Synonym
fecundity, subfertility

Health condition

subfertiliteit

Research involving

(Surplus) Embryos

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: NutsOhra

Intervention

Keyword: Birth weight, Culture medium, IVF, Live birth rate

Outcome measures

Primary outcome

Live birth rate

Secondary outcome

Embryo development, implantation rate, clinical pregnancy rate, miscarriage rate, ongoing pregnancy rate, multiple pregnancy rate, morphometric parameters of foetal development at 8, 12 and 20 weeks of pregnancy, mean values of maternal serum markers during first trimester screening, mean birth weight, mean gestational age at birth and percentage of children with congenital abnormalities.

Study description

Background summary

A variety of embryo culture media are currently used in human in vitro fertilization procedures (IVF). Previous studies have indicated that alterations in the composition of the culture media can affect embryo quality, pregnancy rates and foetal growth. At the beginning of IVF a single culture medium was used for all embryonic stages, while later on it was recognized that the embryo has different needs during the early and late preimplantation stages. This has led to the development of sequential culture media; two media with different ingredients for different days of culture. These media were the most widely used. Recently however, also with the introduction of time-lapse

imaging, the popularity of single step media is increasing again, but proper studies comparing the outcomes of these media that differ in composition, are missing.

Study objective

To compare two internationally widely used IVF culture media, the sequential culture medium G5 (G1.5 for culture on day 1-3 and G2.5 for day 4-6) from Vitrolife (Sweden) and a single step Continuous Single Culture Medium (CSCM) from Irvine (Ireland), to find out which one leads to the best live birth rate per patient and to investigate their effect on perinatal outcome of the resulting children.

Study design

A multi-center, randomized, double-blinded comparison of G5 and CSCM for human preimplantation embryo culture.

Intervention

The IVF treatment (clinical and laboratory procedures) will be performed as usual in each clinic. Randomization will decide in which commercially available culture medium (either G5 or CSCM) to culture all oocytes and resulting embryos of each patient. Only the first cycle is included in this study. In second or subsequent cycles the culture medium of choice in each IVF laboratory will be used.

Study burden and risks

After providing written consent, there is little burden or benefit for the participating women. These women follow normal routine IVF procedures, and, if a pregnancy occurs, normal routine pregnancy evaluations. The only effort consists of filling in a *pregnancy and delivery*-log after the pregnancy screenings at around 8, 12 and 20 weeks of pregnancy and after delivery. Both culture media are certified and used extensively both in the Netherlands and abroad.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX

NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

All couples that present to one of the participating centres for an IVF/ICSI treatment.

Exclusion criteria

Patients undergoing a PGD cycle, patients undergoing a modified natural cycle, patients requiring gestational surrogacy and patients who participated in the study before will be excluded.

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2015
Enrollment:	1980
Type:	Actual

Medical products/devices used

Generic name:	culture medium
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-12-2014
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	20-10-2015
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-12-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-09-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-03-2018
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	03-10-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-12-2018
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

ID: 29477
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50712.000.14
OMON	NL-OMON29477