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Comparison between two commercially available embryo culture media

Submission date	Recruitment status	[_] Prospectively registered
03/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/03/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/03/2009	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A prospective randomised sibling-oocyte study of two sequential media for culturing cleavage stage embryos

Study objectives
Commercially available culture media are expected to be equally efficient in fertilisation and culture of early embryos.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Örebro läns landsting) (Sweden) gave approval on the 25th March 2003 (ref: 90/03)

Study design
Prospective randomised single centre single-blinded (patients only) sibling study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Infertility

Interventions
The study included two commercially available sequential media for fertilisation and culture of oocytes. One of the media system was standard in our clinic, while the other media system was standard in the private clinic in our town. It was not expected that there would be a difference.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Fertilisation rate, measured at 1 day
2. Polynuclei rate, measured at 2 days
3. Cleavage rate, measured at 2 days

Secondary outcome measures
1. Positive human chorionic gonadotrophin (hCG) rate, measured at 1 - 2 weeks.
2. Clinical pregnancy rate, measured at 12 weeks
3. Implantation rate, measured at 12 weeks
4. Delivery rate, measured at 9 months

Overall study start date
01/10/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
All oocytes from patients (aged 24 - 40 years, female) undergoing in vitro fertilisation (IVF) treatment

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
110 patients/1200 oocytes

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Women's and Children's Health
Uppsala
Sweden
751 85

Sponsor information

Organisation
Uppsala County Council (Uppsala Läns Landsting) (Sweden)

Sponsor details
Kvinno och Barndivisionen
Akademiska sjukhuset
Uppsala
Sweden
751 85

Sponsor type
Government

Website
http://www.lul.se/

ROR
https://ror.org/01dv86r63

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Uppsala University Hospital (Sweden) - Centre of Reproduction

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration