Immunological determinants of human embryo implantation: an ex vivo model

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neoplastic and ectopic endocrinopathies
Study type	Observational non invasive

Summary

ID

NL-OMON29908

Source
ToetsingOnline

Brief title
Immunological factors of implantation

Condition

- Neoplastic and ectopic endocrinopathies
- Abortions and stillbirth
- Sexual function and fertility disorders

Synonym
implantation, infertility

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,NWO-AGIKO Stipendium September 2005

Intervention

Keyword: cytokines, human embryo, implantation, IVF

Outcome measures

Primary outcome

The surplus embryos will be cultured on a layer of endometrial stromal cells. The process of adhesion and invasion will be closely followed by measurements of cytokine and trophic factors in culture media, which will provide information on stromal invasion. Main study parameters will be the extent of trophoblast invasion and the cytokine and trophic factor profile of daily produced affluent. Study endpoint will be day 10 of embryo development.

Secondary outcome

- The correlation of cytokine/trophic factor patterns expressed in (autologous co-) culture media from normal and abnormal stromal invading embryos.
- To investigate whether the chromosomal constitution of the embryo is related to a specific pattern of cytokine expression and implantation.

Study description

Background summary

Subfertility affects 15% of couples trying to conceive. Many underlying causes of infertility can be overcome by assisted reproductive technologies (ART). However, despite recent advances in in-vitro fertilisation (IVF) pregnancy rates remain only 20-30% per embryo transfer procedure. Failure of implantation therefore remains a major challenge. Implantation is a complex process in which molecular cross-talk between embryo and endometrium occurs, resulting in apposition, adhesion and invasion of the embryo into the endometrial stroma. An accumulating body of evidence suggests that both implantation and uterine receptivity are controlled primarily, although not exclusively, by locally acting growth factors and cytokines. Further improvement of ART depends on

better understanding of the embryonic-uterine ensemble at the site of implantation. The application of ex vivo models provides a powerful tool to dissect the molecular, cellular and physiological mechanisms of embryo implantation in the human. Here we propose to employ a newly developed model to study stromal invasion of an embryo ex vivo.

Study objective

We intend to employ an ex vivo model of human implantation to study the factors involved in successful implantation. By linking parameters of successful implantation with embryo quality markers, we aim to improve embryo selection and IVF outcomes. It is our objective to improve embryonal screening methods, achieve higher pregnancy rates and improve safety in women undergoing IVF.

Study design

The study design is a prospective, observational study. Firstly we will establish and implement the newly developed ex vivo model, and then exploit it for further experiments in the second stage.

Study burden and risks

Endometrial biopsy is a minimally invasive procedure that is practicable on an out-patient basis. Previous studies have demonstrated that this procedure can be safely performed in the luteal phase of the previous cycle, without affecting pregnancy rates in IVF (Mercader 2003, Spandorfer 2004). This study will not interfere with the standard IVF and embryo transfer procedures and will only use surplus embryos. Therefore the study doesn*t affect pregnancy success rates, nor will it risk the women*s or child*s health.

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

IVF or ICSI treatment

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2007
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-10-2008
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	NL12481.000.06