Implantation failure as a cause of unexplained infertility; determinants of the successrate in ART in women with unexplained infertility.

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We will assess the correlation between the incidence of early pregnancy loss and the successrate of ART in women with unexplained infertility. We will also investigate the difference in the incidence of early pregnancy loss in women with unexplained...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Observational non invasive

Summary

ID

NL-OMON29894

Source
ToetsingOnline

Brief title
Embryo implantation and unexplained infertility

Condition

- Sexual function and fertility disorders

Synonym
idiopathic subfertility, unexplained infertility

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: embryo, implantation, infertility, unexplained

Outcome measures

Primary outcome

The main study parameters are:

• ßHCG levels in urine

• Cytokine expression in endometrial secretion/ culture

The main study endpoint is:

• Cumulative pregnancy rate

• Early pregnancy loss rate

• The embryo secretion cytokine expression profile

• The endometrial secretion cytokine expression profile before embryo transfer.

Secondary outcome

The secondary study parameters are:

• Lifestyle factors: physical exercise, smoking, use of caffeine and alcohol,

BMI (body mass index)

• uNK cell count, endometritis

• PI van de a uterina before ET

The secondary study endpoints are:

• Correlation between secondary study parameters and diagnosis of unexplained

infertility

• Early pregnancy loss rate

Study description

Background summary

Subfertility is defined as failure to conceive a clinical pregnancy after 1 year of unprotected intercourse. In up to 30% of couples presenting with subfertility, no cause is found on routine infertility investigation (Hull et al., 1985). Current standard investigation is limited to analysis of ovarian ovulatory function, patency of the fallopian tubes, semen quality and in some centres, quality of cervical mucous-sperm interaction. The possible role of abnormalities in endometrial receptivity and implantation as underlying causes of subfertility continue to be largely ignored, partly due to the absence of appropriate tests and effective interventions.

Study objective

We will assess the correlation between the incidence of early pregnancy loss and the successrate of ART in women with unexplained infertility. We will also investigate the difference in the incidence of early pregnancy loss in women with unexplained infertility versus normal fertile women.
Additionally, the endometrial cytokine expression profile in women with unexplained infertility versus a reference groep of women undergoing ICSI (male factor) who achieved a pregnancy during study 05-225K, will be studied.

Study design

The study design is a prospective, mono-centre, case-control study.

Study burden and risks

Women with unexplained infertility will collect urine samples during the time on the waiting list to detect an early pregnancy loss. Since most women are curious to know whether an early pregnancy has occurred, we do not expect the burden to be to high. Fertile women will also collect urine samples for three months (from cycle day 14 onwards).

The theoretical risk associated with the aspiration of endometrial secretion before embryo transfer might be disruption of embryo implantation. However, our group has developed a technique which, as we have previously shown, does not disrupt the process of implantation (van der Gaast et al., 2003).

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

Study group
• Women with unexplained infertility after routine fertility and PEPSI screening.
• Women who will start their first IVF treatment cycle. ;Definition unexplained infertility:
• There must be a regular cycle (between 21-42 days),
• normal semen analysis (VCM > 10 million, normal morpholohy > 14%),
• no tubal factor (no abnormalities on hysterosalpingografy and negative CAT) and
• no abnormlaities on the hysteroscopy (partial septum, submucosal/Intramural fibroids, endometrial polyps, adhesions, chronic and acute endometritis: diagnosed by the pathologist)
• no abnormalities from blood screening: FSH < 10, no anticardiolipin antibodies/ lupus anticoagulant/ Factor V Leiden mutation/ prothrombin gene mutation/ deficiencies in protein S/ protein C and antithrombin, no abnormal TSH. ;Reference group normal implanters (only

data will be used)
• Women who have conceived after ICSI treatment for male factor infertility.
• Women who were included in study 05/225-K.;Reference group normal fertile women
• Women who have never showed any fertility disorders (preferably already conceived and delivered).

Exclusion criteria

Study group
• PESA (percutaneous epididymal sperm aspiration) / MESA (microsurgical epididymal sperm aspiration / TESE (testicular sperm extraction)
• Difficulty in communicating in Dutch or English
• Women older than 37 years;Reference group of normal fertile women
• Women older than 37 years
• Women who have already tried to conceive for more than four months/ who have had any fertility disorders in the past.;Exclusion criteria for endometrial secretion aspiration:
• Excisional procedures to treat cervical intraepithelial neoplasia and no previous uncomplicated ET/IUI.
• Previous ducumented difficult intra uterine inseminations

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-08-2006
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	18-07-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	Na goedkeuring METC zal de trial geregistreerd worden bij clinicaltrials.gov.
CCMO	NL12321.041.06