Oocyte vitrification in women at risk of ovarian failure; an observational study with follow-up of children

Published: 02-03-2010
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To determine safety and efficacy of oocyte vitrification.

Ethical review	Not approved
Status	Will not start
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON35039

Source
ToetsingOnline

Brief title
Oocyte vitrification

Condition

- Congenital and hereditary disorders NEC

Synonym
birth defect, congenital malformations

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Congenital Abnormalities/epidemiology*, Cryopreservation*, Oocytes*

Outcome measures

Primary outcome

Primary outcome is the number of congenital abnormalities in babies born after oocyte vitrification (%).

Secondary outcome

Secondary outcomes are the number of oocytes retrieved and vitrified per woman started (%), The number of women returning for thawing of oocytes (%), the live birth rate in women undergoing oocyte vitrification (%), the live birth rate per thaw cycle (%), the number of oocytes surviving the freeze-thaw process (%), the fertilisation rate (%), embryo development, number and type of pregnancy outcome (biochemical-, clinical-, ongoing-, multiple pregnancy rate (%) after freeze-thaw process.

Furthermore the live birth rate after natural conception in the same risk group (%), women never becoming pregnant (%), the number of congenital abnormalities after spontaneous attempts (%), the number and type of pregnancy outcome (biochemical-, clinical-, ongoing-, multiple pregnancy rate after spontaneous attempts (%).

Study description

Background summary

Women of reproductive age at risk of ovarian failure, defined as loss of ovarian function might benefit from oocyte vitrification to increase chances of future motherhood. Oocyte vitrification, or ultra rapid egg freezing is a relatively new technology with promising initial results. Worldwide over 900 babies have been born after egg freezing, of which 392 after oocyte vitrification. In these babies, no apparent increase in congenital anomalies was found. We aim to establish safety and efficacy of oocyte vitrification by performing a large observational cohort study with follow up of women and children.

Study objective

To determine safety and efficacy of oocyte vitrification.

Study design

Observational cohort study

Study burden and risks

After a standard IVF/ICSI cycle, i.e. a 3-week period with controlled ovarian hormonal stimulation, ultrasound monitoring (4-5 times), endocrine monitoring (4-5 times) and transvaginal follicle aspiration, oocytes are retrieved and mature metaphase II (MF II) oocytes are vitrified using the Cryotop method. They are stored for future use, when,- upon the request of the woman concerned- these oocytes will be thawed, fertilized with intracytoplasmic sperm injection (ICSI) and transferred to the uterus, with the intent of creating a successful pregnancy. The risks to the women are limited to the risks associated with the IVF/ICSI procedure such us ovarian hyperstimulation syndrome and infection, and the risk of hitherto unknown complications of oocyte vitrification.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Oocyte vitrification will be offered to women at risk of ovarian failure due to iatrogenic gonadotoxic treatment or due to increasing age, as well as to women undergoing IVF/ICSI in whom unexpectedly no spermatozoa can be obtained at the time of follicle aspiration.;Inclusion criteria;1. Women between the age of 16 and 40 years who are at risk of ovarian failure due to iatrogenic gonadotoxic treatment (cancer treatment);2. Women between the age of 30 and 40 years who are at risk of ovarian failure due to increasing age. ;3. Women between the age of 18 and 42 years undergoing IVF/ICSI during which no spermatozoa can be obtained at the time of follicle aspiration.

Exclusion criteria

1. Women with borderline or invasive ovarian cancer.
2. Women with contraindications for IVF treatment such as cardiovascular-pulmonary disease, severe diabetes, bleeding disorders, immunodeficiency, morbid obesity, and premature ovarian failure.
3. Women with severe psychopathology, severe anxiety and inability to cope.
4. Women who are, at the time of the requested thawing of their oocytes, above the age at

which embryo transfer is considered safe: currently 45 years of age (modelreglement embryowet 2003)
5. Not able or willing to provide informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	190
Type:	Anticipated

Ethics review

Not approved

Date:	02-03-2010
Application type:	First submission
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	NL30772.000.10