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

Published: 29-11-2011
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To determine safety 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-OMON34190

Source
ToetsingOnline

Brief title
Oocyte vitrification

Condition

- Congenital and hereditary disorders NEC
- Reproductive tract 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 requesting the use of their vitrified oocytes (%), the number of oocytes surviving the freeze-thaw process (%), the fertilisation rate (%), the percentage of top quality embryos (%), number and type of pregnancy outcome (biochemical-, clinical-, ongoing-, and multiple pregnancy rate (%)) after transfer of freeze-thawed and fertilized oocytes, the live birth rate in women undergoing oocyte vitrification (%), the live birth rate per thaw cycle (%). Also, the number of women desiring children (%), live birth rate after natural conception in the group under study (%), women intending to become pregnant but failed (%), the number of congenital abnormalities after natural conception (%), and the number and type of pregnancy outcome (biochemical-, clinical-, ongoing-, multiple pregnancy rate (%) after natural conception will be investigated.

Study description

Background summary

The aim of the study is to determine the safety of oocyte vitrification, by means of an observational cohort study. The children born after oocyte vitrification will be followed.

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 of oocyte vitrification.

Study design

Observational cohort study.

Study burden and risks

Although no increased risk is of congenital abnormalities is known in children born after oocyte vitrification hitherto, a larger amount of children need to be studied.

The burden of participation equals the burden of 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. The risks to the women are limited to the risks associated with the IVF/ICSI procedure such as ovarian hyperstimulation syndrome and infection.

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

1. Women until their 40th birthday who are at risk of ovarian failure due to iatrogenic gonadotoxic treatment.
2. Women until their 40th birthday who are at risk of premature ovarian failure and women between the ages of 30th and 40th birthday who are at risk of ovarian failure due to increasing age.
3. Women until their 43rd birthday undergoing an IVF/ICSI cycle 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 reach, at the time they request thawing of their oocyte, the maximum age at which embryo transfer is accepted by Dutch guidelines (currently from their 45th birthday).

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:	1321
Type:	Anticipated

Ethics review

Not approved

Date:	28-12-2010
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	NL33893.000.10