

Fertility follow-up of women who visited the outpatient fertility ward for information on fertility preservation before starting gonadotoxic treatment

Published: 11-07-2013

Last updated: 24-04-2024

Fertility follow-up of the women who visited our out patient ward for information on fertility preservation before starting gonadotoxic treatment

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON38726

Source

ToetsingOnline

Brief title

Fertility after gonadotoxic treatment

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Pregnancy, labour, delivery and postpartum conditions
- Sexual function and fertility disorders

Synonym

infertility

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: fertility, follow-up, gonadotoxic treatment

Outcome measures

Primary outcome

Number of pregnancies after gonadotoxic therapy (including miscarriages and ectopic pregnancies). Live born children. The occurrence of premature ovarian failure. The use of assisted reproductive therapy.

Secondary outcome

Patient experience with treatment and results (number of frozen embryo*s)

Study description

Background summary

Post-treatment fertility is rated as very important by women who receive gonadotoxic therapy. Chemotherapy is one of the main causes of premature ovarian failure in this population. One way to preserve fertility is to cryopreserve embryo*s. In the Leiden University Medical Center (LUMC) is embryocryopreservation offered to women previous to gonadotoxic therapy.

Study objective

Fertility follow-up of the women who visited our out patient ward for information on fertility preservation before starting gonadotoxic treatment

Study design

Survey study

Study burden and risks

Except from possibly some stress induced by the questionnaires no risks are expected

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Women in the reproductive age visited our outpatient ward between January 2005 and January 2011 for consultation about embryo cryopreservation, before gonadotoxic therapy

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 11-07-2013

Enrollment: 72

Type: Actual

Ethics review

Approved WMO

Date: 11-07-2013

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 24-09-2013

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL44144.058.13