Retro-PROFIT; PReservation Of female Fertility In oncologic Treatment Fertility, pregnancy and quality of life after fertility-sparing treatment for gynaecological cancer.

Published: 19-10-2022
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Primary Objectives: Determine oncologic outcomes after fertility-sparing treatment in AYAs with cervical, ovarian or endometrial cancer (Q1). Determine fertility and obstetric outcomes after fertility-sparing treatment in AYAs with cervical, ovarian...

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

Summary

ID

NL-OMON53845

Source
ToetsingOnline

Brief title
Retro-PROFIT; PReservation Of female Fertility In oncologic Treatment

Condition

- Reproductive neoplasms female malignant and unspecified
- Pregnancy, labour, delivery and postpartum conditions
- Sexual function and fertility disorders

Synonym
cervical cancer, endometrial cancer, gynaecological cancer, ovarian cancer

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF kankerbestrijding

Intervention

Keyword: Adolescents and young adults (AYAs), fertility preservation, gynaecological cancer, quality of life

Outcome measures

Primary outcome

Q1: 2-year and 5-year recurrence free survival

Q2:Percentage of women trying to conceive, within this group: pregnancy rate (number of first pregnancies after treatment divided by the number of women who tried to conceive) and number of pregnant women divided by the number of women who tried to conceive after treatment.

Live birth rate

Q3:Initiation of pursuing pregnancy

Psychological outcome: reproductive concerns, anxiety and depression, cancer worries and decisional regret.

Secondary outcome

Q1: 2- and 5-year survival and overall survival Q2:Type of conception (artificial or spontaneous) Miscarriages, gestational age at delivery (preterm <28 weeks, preterm 28-32 weeks, preterm 32-37 weeks, term), mode of delivery

(induction, caesarean section, spontaneous labor)

Study description

Background summary

Every year, approximately 350 women between 18-39 years old are diagnosed with cervical, ovarian or endometrial cancer in the Netherlands. This age group is called AYAs (adolescents and young adults). Due to early detection and advancements in cancer treatment, survival of patients has improved. As a result, the focus of oncologic treatment has expanded from survival only, towards quality of life (QoL) after surviving cancer. Preservation of fertility is an important factor to achieve good QoL in AYAs. However, fertility can be impaired by surgery or gonadotoxic effects of cancer treatment. Therefore, fertility-sparing treatment could be offered to patients with early stage disease and the wish to preserve fertility. However, data on oncological safety and obstetrical outcomes after these procedures are scarce and based on small retrospective series. Furthermore, the majority of these women eventually decide not to pursue pregnancy after fertility-sparing treatment. The factors that influence these decisions regarding fertility-sparing treatment and pursuit of a subsequent pregnancy, and the psychological consequences of these choices are unknown. With this study, we will create a large national retrospective database on oncologic, obstetric and psychologic outcomes after fertility-sparing treatment in gynaecological cancers. This will provide sufficient data to help future AYAs to make a well-informed decision on their preferred cancer treatment in the light of oncological and psychological consequences of the chosen treatment modality.

Study objective

Primary Objectives:
Determine oncologic outcomes after fertility-sparing treatment in AYAs with cervical, ovarian or endometrial cancer (Q1).
Determine fertility and obstetric outcomes after fertility-sparing treatment in AYAs with cervical, ovarian or endometrial cancer (Q2).
Determine factors that influence initiation of pursuing pregnancy, and psychological outcomes in AYAs with cervical, ovarian or endometrial cancer (Q3).

Study design

National, multicentre, retrospective and cross-sectional study. Collection of data using electronic health records (EHRs), self-report questionnaires,

semi-structured interviews.

Study burden and risks

Participation is not associated with any risks. A psychological burden could be experienced by filling out the questionnaires, since the questions are related to fertility, (possible unfulfilled) pregnancy wish, concerns, and regret. However, participation is voluntary, and patients can withdraw from participation at any time. The duration of all (online) questionnaires is 30-45 minutes (Q2/Q3). The interview study will take maximum of 45 minutes. 48 women and 12 partners will be invited. These interviews take place on location or via teams. The interviews with the partner will be held seperately.
There are no direct benefits for participants in this study. However, with their participation they contribute to the collection of important data to improve the care of future AYAs with a wish to preserve fertility after cancer treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Women with cervical, ovarian or endometrial cancer
- Age between 18-39 at time of diagnosis
- Fertility-sparing treatment between 2000 and 2020

Exclusion criteria

For the questionnaire and interviewstudy:
- Living abroad and untraceable at time of data collection
- Deceased at time of data collection
- Insufficient understanding of the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-11-2022
Enrollment:	1030
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	19-10-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-08-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-09-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-11-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-12-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-03-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	05-08-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL80232.058.22