Evaluation of quality of oncofertility care in young female cancer patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON50410

Source
ToetsingOnline

Brief title
Quality of oncofertility care

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Oncofertility care

Health condition

Vruchtbaarheid na oncologische behandeling

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie en Obstetrie
Source(s) of monetary or material Support: Particulier fonds

Intervention

Keyword: Oncofertility, Quality of care, Young female cancer patients

Outcome measures

Primary outcome

Primary outcome measures:

Percentage of patients who received information on the risk of infertility and

the percentage of women, if desired, who were referred to a gynaecologist.

Secondary outcome

Secondary outcome measures:

Patients experiences with oncofertility care and counseling.

Patients' involvement in decision making in fertility preservation.

Quality of life

Decisional conflict

Decisional regret

Reproductive concerns.

These last four outcomes will be measures by means of validated questionnaires.

Study description

Background summary

In the Netherlands around 2600 female adolescents and young adults (AYA, 18-40 years) are yearly diagnosed with cancer. Advancements in early detection and treatment of cancer lead to higher rates of cancer survivorship. Therefore,

attention should not only be paid to survival but also to the late side effects of cancer treatment and long-term quality of life issues. One important undesirable side effect of cancer treatment in these young women is the potential loss of fertility (risk varies from low <20% to high >80%). The optimal care for these women, as recommended in evidence based guidelines, starts with information provision by her oncological caregiver, then, if desired, referral to and counseling by a fertility specialist, and ends with decision-making whether she wants to preserve her fertility or not. Providing information to women in the reproductive age newly diagnosed with cancer on both the risk of infertility due to gonadotoxic treatment as the fertility preservation options affects quality of life positively, reduces long-term regret and reduces concerns regarding fertility. Unfortunately, studies have shown that despite several guidelines and recommendations on fertility preservation not all patients receive information on their infertility risks and options to preserve fertility. The referral process to a fertility specialist is often inadequate as well, illustrating a need for better guideline adherence and improvement of oncofertility care. Indeed, for women with unmet informational needs on fertility preservation options before the start of their oncological treatment, the threat of infertility can lead to long-term distress and adversely affects quality of life.

Study objective

We aim to get insight in the actual quality of oncofertility care in young females with cancer. With this insight we can identify barriers and develop a strategy to improve quality of oncofertility care and thereby quality of life for young female cancer survivors.

Study design

A retrospective cohort study on 2016 and 2017.
Duration of study: 5 months

Methods:
Actual quality of oncofertility care in young women with cancer will be measures in four hospitals: Radboudumc (Nijmegen), het Amsterdam UMC, het EramusMC, het Maastricht UMC, Leiden UMC, Canisius Wilhelmina Hospital (Nijmegen), Rijnstate Hospital (Arnhem) and Jeroen Bosch Hospital (Den Bosch). Quality of care will be measured in four domains of oncofertility care, namely risk communication by oncological caregiver, referral to the gynaecologist, counseling by the gynaecologist and the decision-making by the patient. Patients who are diagnosed in 2016 or 2017 with cancer will be identified by the IKNL (dutch cancer registration) after permission of their oncological caregiver. De oncological caregiver will further select the patients based on the in- and exclusion criteria and they will assess if the patiënt is emotionally and physically able to receive the questionnaire. If the

oncological caregiver doubts, the patiënt will not be invited.
Identified patients will receive a participation letter from their oncological caregiver together with the information letter and informed consent form.
If the patient sents her informed consent to the researcher, they will be sent a questionnaire. After 3 weeks patients will receive one reminder when they did not return the questionnaire.

When we identified the actual quality of oncofertility care we have insight into the barriers. Hereafter we will develop an improvement strategy that will focus on as well patients, as caregivers (doctors, specialized nurses, nurses) as the organization.

Research questions:
1. What is the actual quality of oncofertility care in information provision, referral, counseling and decision-making?
2. Which improvement strategy can be developed to improve the quality of oncofertility care?

Study burden and risks

Possible advantage: A better quality of oncofertility care for future patients.
Risks: There are no risks in participation in this study.
Burden: Women of reproductive age who were diagnosed with cancer in 2016 or 2017 will be asked for filling in one questionaire which will take 30 minutes of their time. The expected burden for women participating in this study will be not physical, however a psychological burden can be experienced by filling in the questionnaires, especially if they feel/realize they did not get (enough) information about fertility preservation or experienced decisional conflict. We hope to minimize this burden by telling that participation is voluntary and that a woman can decide to stop with the study without consequences. Furthermore, psychological support will be offered when women experience a psychological burden.

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

- Women aged 18-40 years old, cancer diagnosis in 2016 or 2017
- received gonadotoxic treatment
- emotionally and physically able to receive a questionnaire

Exclusion criteria

- Women who did not receive a gonadotoxic treatment
- patient has had surgery in which her reproductive organs were removed (ovaries, uterus)
- Not understanding the Dutch or English language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2018
Enrollment:	780
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-09-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	06-07-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL61570.091.17

Study results

Date completed:	02-10-2021
Actual enrolment:	121

Summary results
Trial is onging in other countries