

# Preservation of fertility in female AYA cancer patients: needs assessment, fertility, and quality of life in cancer survivors; 2-PREFER study

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Determine AYA\*s experiences and needs related to FP(C) and follow-up care after FP(C) (Q1); determine the number of AYAs pursuing to conceive and their fertility and obstetric outcome(s) after FP(C) after gonadotoxic treatment (Q2); determine...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON57201

### Source

ToetsingOnline

### Brief title

2-PREFER study

### Condition

- Other condition
- Reproductive tract disorders NEC

### Synonym

Fertility preservation

### Health condition

psychische symptomen, waaronder angst en depressieve symptomen

## **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:** counselling, fertility preservation, needs-assesment, oncology

## **Outcome measures**

### **Primary outcome**

Patients experiences and needs related to FPC and follow-up care after FP(C), assessed with self-report questionnaires, and semi-structured interviews (Q1);

The fertility and obstetric out-come(s), percentage of AYAs pursuing to conceive (both with and without reproductive assis-tance) post gonadotoxic treatment, and within this group the pregnancy rate and live birth rate, assessed with self-report questionnaires (Q2); Initiating of pursuing pregnancy (yes/no) and pursuing pregnancy (months of trying to conceive); psychological factors (: anxiety- and depression levels, reproductive concern, cancer worries and decisional regret), relational fac-tors (: relationship status and duration), biographical (:age, BMI, intoxications), somatic (: medical history) are assessed with validated self-report questionnaires (Q3). Additional, we will further explore these psychological factors related to the (initiating of) pursuing pregnancy in semi-structured interviews (Q3).

### **Secondary outcome**

Psychological distress (anxiety and depression), desire for children; and possible mediators: reproductive concerns, gender identity concerns, and

self-esteem, are assessed with validated self-report questionnaires. The moderator, parenthood status is defined by whether the AYA is a parent (yes/no) (Q4)

## Study description

### Background summary

With better survival rates for female Adolescents and Young Adults (AYA) patients diagnosed with cancer, more attention has been paid to future risks such as fertility decline due to gonadotoxic treatment. Fertility preservation counselling (FPC) and eventually fertility preservation (FP) is offered to these AYA patients that face a gonadotoxic treatment. Little is known about AYA\*s needs related to follow-up care after FP(C), including the psychological effects of facing potential fertility decline. Furthermore, usage rate of cryopreserved material is relatively low and the majority of these women eventually decide not to pursue pregnancy after FP. The factors that influence these decisions regarding pursuit of a subsequent pregnancy, and the psychological consequences of these choices are unknown.

### Study objective

Determine AYA\*s experiences and needs related to FP(C) and follow-up care after FP(C) (Q1); determine the number of AYAs pursuing to conceive and their fertility and obstetric outcome(s) after FP(C) after gonadotoxic treatment (Q2); determine factors in AYAs that may be associated with (initiation of) pursuing pregnancy (Q3) and secondary, exploring factors that are associated with psychological distress and desire for a children among AYAs (Q4). In this overarching project we aim to develop a standard set of Patient Reported Outcome Measures (PROMs), regarding to the counseling-, treatment- and follow up procedure of AYA patients that face a gonadotoxic treatment. With these PROMs we aim to develop validated questionnaires to implement in a Value Based Health Care (VBHC) pathway. These, and PROMs at counseling and treatment will be used to develop a VBHC pathway; we believe that such a VBHC pathway will help in optimizing the experiences and needs of AYA patients in all phases encompassing FP.

### Study design

Single centre retrospective and cross-sectional study. Collection of data using electronic health records (EHRs) and self-report questionnaires in phase 1, and

semi-structured inter-views in phase 2.

### **Study burden and risks**

Participation is not associated with any risks. A psychological burden could be experienced by filling out the questionnaire or participating in the interview, 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 the (online) questionnaire is 30-45 minutes (Q1/Q2/Q3/Q4), and the duration of the interview is +- 45 minutes (Q3).

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 future 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, who underwent potentially gonadotoxic treatment (chemotherapy and/or radio-therapy) because of diagnosis of cancer
- age between 18-39 years at time of FPC
- Visited the fertility clinic of the LUMC for FP(C) between 2012- 2023

## Exclusion criteria

- Non-curabel treatment
- Living abroad and untraceable at time of data collection
- Deceased at time of data collection or
- Insufficient understanding of the Dutch 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: Pending

Start date (anticipated): 01-01-2025

Enrollment: 250

Type: Anticipated

### Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 23-12-2024

Application type: First submission

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	NL86853.058.24