COMPRehensive assessment of prevalence, risk factors and mechanisms of impaired medical and psychosocial health outcomes among Adolescents and Young Adults with cancer: the prospective observational COMPRAYA cohort study

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To examine the prevalence, risk factors and mechanisms of impaired health outcomes (short- and long-term medical and psychosocial effects and late effects) over time among a population-based sample of AYA cancer patients.Primary Objective: - To...

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

Summary

ID

NL-OMON54428

Source
ToetsingOnline

Brief title
COMPRAYA cohort study

Condition

- Other condition

Synonym
tumor; carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek (AVL)
Source(s) of monetary or material Support: KWF

Intervention

- No intervention

Keyword: cancer, health outcomes, risk factors, young adults

Explanation

N.a.

Outcome measures

Primary outcome

The main outcomes are medical (e.g. second tumour; survival; fertility) and
psychosocial (e.g. distress) health outcomes. Other study parameters
(covariates/moderators/mediators) are characteristics of the individual (e.g.
age, sex, cultural background, partner status, educational level, occupation,
tumour type, disease stage, body composition, comorbid conditions, coping
style), characteristics of the environment (e.g. cancer treatment, lifestyle),
and genetic and biological factors (e.g. family history of cancer, stress and
inflammation markers (e.g. cortisol, IL-6), microbiome).

Primary Objective:
- To identify individual, environmental, biological and psychological
characteristics of AYA cancer patients who are at high risk for impaired
medical and psychosocial health outcomes. In other words: To develop a
prediction model for impaired medical and psychosocial health outcomes (at
baseline, 2-, 5- and 10-year follow-up).

Secondary outcome

Secondary Objective(s):
-To assess the prevalence of impaired (age-specific) medical (e.g. second
tumour) and psychosocial (e.g. social isolation) health outcomes at each time
point (at baseline, 2-, 5- and 10-year follow-up).

Exploratory Objective(s):
-To analyse the course of medical and psychosocial health outcomes over time

(all timepoints needed)
-To analyse mediating mechanisms associated with impaired health outcomes in
AYA cancer patients (at baseline, 2-, 5- and 10-year follow-up).

Other Objective(s):
-To form a prospective observational cohort of patients diagnosed with cancer
at AYA age, and follow them over time until death. </p>

Study description

Background summary

Childhood cancer survivorship attracts attention globally, because successes in treatment have led to increasing number of survivors who reach adulthood, in which survivorship issues affecting health-related quality of life (HRQoL) become prominent. Most pediatric patients are treated intensively with irradiation and/or chemotherapy which put them at risk for early and/or late adverse medical and psychosocial events. In contrast, much less is known from adolescent and young adult (AYA) cancer patients, diagnosed between 18-39 years, who, with an 80% chance to survive, also have a long life ahead. AYA cancer patients, much more than children, suffer from delay in diagnosis, lack of centralization of care, age-adjusted expertise (*I am treated like my 74-year-old aunt*) and AYA follow-up care. AYAs typically present with a rare tumor: either with a paediatric malignancy (e.g. acute lymphoblastic leukaemia, paediatric brain tumors), a tumor of AYA age (e.g. Hodgkin*s disease, germ cell cancer, melanoma, thyroid cancer) or, unexpectedly, with an adult tumor (e.g. gastrointestinal, lung, breast carcinomas). Next to these differences in epidemiology, tumor biology, developmental challenges (e.g. forming relationships, becoming financially independent, having children) and treatment regimens differ between AYAs and children, and therefore findings derived from childhood cancer survivors cannot be extrapolated to AYAs. Furthermore, novel treatments with targeted agents or immunotherapy are more likely to be administrated to AYAs compared to children. Finally, a rare group of incurable AYA cancer patients will survive for many years, for whom health outcome and supportive care intervention data are lacking.

(Inter)nationally, cohort studies exist that address many relevant issues, but all from the perspective of tumor histology, rather than an AYA age-specific perspective. These tumor-specific cohorts do not specifically address unique issues such as:
(1) Age-specific health outcomes like fertility, late toxicity, family functioning, employment;
(2) Genetic risk factors and AYA tumor genetics;
(3) Tumor types with an incurable, protracted behaviour at this young age;

(4) Age-adjusted early interventions

Globally, so far, the identification of AYA patient subgroups that might be more susceptible to poor health outcomes has not been systematically addressed. The role of sociodemographic and treatment-associated risks, external exposures (e.g. lifestyle) and host factors (e.g. genetic, biological, physiological); or combinations of influences for impaired (age-specific) health outcomes, remains largely unknown. Understanding who is at risk and why will support the development of evidence-based AYA prevention, treatment and supportive care programs and guidelines, in co-creation with AYA cancer patients.

Study objective

To examine the prevalence, risk factors and mechanisms of impaired health outcomes (short- and long-term medical and psychosocial effects and late effects) over time among a population-based sample of AYA cancer patients.

Primary Objective:
- To identify individual, environmental, biological and psychological characteristics of AYA cancer patients who are at high risk for impaired medical and psychosocial health outcomes. In other words: To develop a prediction model for impaired medical and psychosocial health outcomes (at baseline, 2-, 5- and 10-year follow-up).

Secondary Objective(s):
-To assess the prevalence of impaired (age-specific) medical (e.g. second tumour) and psychosocial (e.g. social isolation) health outcomes at each time point (at baseline, 2-, 5- and 10-year follow-up).

Exploratory Objective(s):
-To analyse the course of medical and psychosocial health outcomes over time (all timepoints needed)
-To analyse mediating mechanisms associated with impaired health outcomes in AYA cancer patients (at baseline, 2-, 5- and 10-year follow-up).

Other Objective(s):
-To form a prospective observational cohort of patients diagnosed with cancer at AYA age, and follow them over time until death.

Study design

This is a dynamic prospective study consisting of two study arms namely; COMPRAYA 1.0 and COMRAYA 2.0.

Participating AYAs will be followed over several years to assess their health outcomes. We do this by asking these patients at the individual level to

complete an annual questionnaire. In addition, in COMPRAYA 1.0, hair, blood and stool samples will also be taken together with the measurement og the vital parameters, at three time points, namely in the first 6 months after diagnosis, 2 and 5 years after diagnosis. Participants in COMPRAYA 2.0 will only be asked to give blood once and to complete the questionnaires up to a maximum of 10 years after diagnosis.
Also, if the patient gives permission, medical data from the electronic patient record, the Dutch cancer registry and other health-related registrations will be collected.
Tumor tissue can also be used.

At participating hospitals, AYAs will be invited to participate in COMPRAYA.

COMPRAYA 1.0:
At the start of the study, the AYA will sign a consent form for:
(1) Collection of medical data from the electronic patient record, the Dutch cancer registry and other health-related registries (consent linkage);
(2) Completion of validated questionnaires on (age-specific) health outcomes;

(3) Use of tumor tissue known to PALGA;
(4) Blood collection, storage and subsequent central analysis;
(5) Hair, stool collection, storage and subsequent analysis
(6) Hospital visit to measure vital parameters (body composition, strength);

COMPRAYA 2.0
Based on selection from the NKR, appropriate participants will receive an invitation. They can give consent for participation either digitally or on paper. Following this consent, the participant will be contacted for an appointment to draw blood. The questionnaire can further be completed online or on paper.

Study burden and risks

On an individual level, patients who participate are asked to complete questionnaires on an annual basis for at least 10 years. All sample collections will take place at three time points: 0-6 months after diagnosis (baseline), 2 and 5 years; except blood for DNA analyses which will only take place at baseline. The collection of blood, hair and faeces at three occasions is minimally invasive and the risks of blood draws, hair and fecal sampling are negligible. All safety measures and procedures will be performed according to local guidelines. Patients will not experience direct benefit from participation in the COMPRAYA study.

By participating, patients will contribute to a better insight in the prevalence of impaired medical and psychosocial (age-specific) health outcomes in AYA and evidence on factors associated with these health outcomes. This will lead to better and more personalized cancer care and supportive care tools for

future AYA cancer patients.

Contacts

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Trial sites

Trial sites in the Netherlands

Antoni van Leeuwenhoek (AVL)
Target size: 450

Amsterdam UMC
Target size: 450

Maxima Medisch Centrum
Target size: 100

Radboud Universitair Medisch Centrum
Target size: 450

Vrije Universiteit Medisch Centrum
Target size: 450

Erasmus MC, Universitair Medisch Centrum Rotterdam
Target size: 450

St. Antonius Ziekenhuis
Target size: 100

Universitair Medisch Centrum Groningen
Target size: 450

Universitair Medisch Centrum Utrecht
Target size: 450

Elisabeth-Tweesteden ziekenhuis
Target size: 100

Maastricht Universitair Medisch Centrum +
Target size: 400

Isala
Target size: 100

Catharina-ziekenhuis
Target size: 100

OLVG
Target size: 100

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- COMPRAYA 1.0 All AYAs diagnosed with cancer for the first time between 18-39 years of age, 3 months ago after diagnosis up to max 6 months after diagnosis in 1 of the participating centers
Mentally competent; sufficient understanding of the Dutch language.

COMPRAYA 2.0 All AYAs diagnosed with cancer for the first time between 18-39 years of age from 1999 to 2022, treated in one of the participating centers
Mentally competent; sufficient understanding of the Dutch language.

Exclusion criteria

- Mentally incompetent patients based on the opinion of treating physician .
- Inability to understand the Dutch language
- Life expectancy less than 6 months based on the opinion of treating physician

- Those already participating in COMPRAYA 1.0 will not be included in COMPRAYA 2.0.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	18-06-2021
Enrollment:	4000
Duration:	120 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	29-09-2020
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	27-05-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-12-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-06-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-11-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-12-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-03-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-09-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-05-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-04-2025
Application type:	Amendment
Review commission:	METC NedMec

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	NL73969.031.20
Research portal	NL-007930