Health-Related Quality of Life and disease-specific symptoms among Lymphoma and Multiple Myeloma survivors: A longitudinal PROFILES registry study. VITA-study

Published: 22-09-2021
Last updated: 27-12-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lymphomas non-Hodgkin's unspecified histology
Study type	Observational invasive

Summary

ID

NL-OMON52363

Source
ToetsingOnline

Brief title
VITA-study

Condition

- Lymphomas non-Hodgkin's unspecified histology
- Lymphomas non-Hodgkin's unspecified histology

Synonym
Lymphoma, Multiple Myeloma

Research involving
Human

Sponsors and support

Primary sponsor: Integraal Kankercentrum Nederland (IKNL)
Source(s) of monetary or material Support: NWO investeringsaanvraag groot

Intervention

Keyword: Lymphoma, Multiple Myeloma, Patient-Reported Outcomes

Outcome measures

Primary outcome

Primary: HRQoL (EORTC QLQ-C30) and disease specific HRQoL/symptoms (EORTC QLQ-LYMPH32 or EORTC QLQ-MY20 + 2 single items from EORTC item library)

Secondary outcome

Secondary: neuropathy (single item from EORTC item library), sexual functioning/intimacy (5 single items from EORTC item library), anxiety and depressive symptoms (HADS), side effects (PRO-CTC-AE), personality (LOT-R and BFI), self-management (HEIQ), coping (SE7), health status (EQ-5D), therapy adherence (MARS) and health-care use.

Study description

Background summary

Currently in the Netherlands, 44.500 patients live with or have survived lymphoma or multiple myeloma (20-years prevalence). Health-related quality of life (HRQoL) after cancer diagnosis and treatment has become more important over the years in these patients because of a favourable survival. In addition, indolent non-Hodgkin lymphoma and chronic lymphatic leukaemia (CLL) are generally regarded more of a chronic disease, remaining present over many years after diagnosis. Previous research identified HRQoL varied by age, sex, comorbid diseases, and the presence of late effects. Besides, several studies indicated lower physical functioning, cognitive functioning, psychological distress, and problems concerning sexuality, fatigue, appetite loss, vitality, and finances in patients with lymphoma. However, the majority of studies about

HRQoL in lymphoma or multiple myeloma is cross-sectional in design, and insight in underlying mechanisms of HRQoL, relying best on longitudinal study designs, is lacking. This study builds upon an ongoing longitudinal study by our research group, assessing HRQoL in lymphoma and multiple myeloma patients from diagnosis to two years after diagnosis, including questionnaires and the Fitbit Inspire (NL20.011). In order to investigate the mechanisms leading to worse QoL outcomes among lymphoma and multiple myeloma patients more thoroughly, we now also aim to include measurements of side effects during active treatment (BijKankerApp), biological factors (blood samples) and environmental factors (food intake).

Study objective

The main objective is to assess HRQoL and (disease-specific) symptoms in patients with lymphoma or multiple myeloma. In addition, to identify demographic, clinical, biological, physiological and environmental characteristics of lymphoma and multiple myeloma patients who are at high risk for poor physical and psychosocial outcomes (general and disease-specific QoL, physical activity, anxiety, depression, health care utilisation, therapy adherence and sleep).

The main research questions of our longitudinal population-based study are:
1. What is the level of HRQoL and symptoms of patients diagnosed with lymphoma or multiple myeloma before, during and up to two years after treatment?
2. What is the role of demographic (age, gender), clinical (disease characteristics, treatment, side effects), physiological (daily activity, heart rate, sleep), biological (blood samples) and environmental (Body Mass Index, food intake) characteristics on HRQoL of lymphoma and multiple myeloma patients and can we identify individuals or groups at risk of lower HRQoL?
3. What is the association of mediating mechanisms (e.g. inflammation levels, body composition, heart rate, physical activity) with poor physical and psychosocial outcomes in lymphoma and multiple myeloma patients? In other words, why is a person at risk?

Study design

Longitudinal population-based study.

Study burden and risks

On an individual level, patients who participate are asked to complete questionnaires at five consecutive points in time, spread over a timeframe of two years. It takes a patient about 30 minutes to complete each questionnaire. No burden is expected here. The collection of blood at three occasions (which takes about 10 minutes per occasion) is considered minimally invasive. Optionally, patients can also choose to wear a Fitbit Inspire (activity

tracker) at 5 points in time, participate in the *BijKankerApp* (at baseline and during active treatment) and/or fill out a food diary at 2 points in time. These activities are considered minimally invasive too. Furthermore, patients can contact an independent doctor for more information about this study.

Contacts

Public
Integraal Kankercentrum Nederland (IKNL)

Zernikestraat 29
Eindhoven 5612HZ
NL
Scientific
Integraal Kankercentrum Nederland (IKNL)

Zernikestraat 29
Eindhoven 5612HZ
NL

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:
- Patients diagnosed with either HL, NHL, CLL or MM
- 18 years or older
- Able to fill out questionnaires Dutch (in terms of language skills and

cognitive abilities).

Exclusion criteria

Patients with severe psychopathology or dementia, and patients in transition to terminal care will be excluded from the study. We will only have our questionnaire in Dutch, so patients who cannot read Dutch will be unable to complete the questionnaire.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2022
Enrollment:	560
Type:	Actual

Ethics review

Approved WMO Date:	22-09-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-11-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	03-01-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	29-06-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	28-11-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-11-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL78561.015.21