Patient reported outcomes in high risk and advanced melanoma patients

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Primary outcome is to assess HRQoL in high risk and advanced melanoma patients treated with immune checkpoint-inhibitors. Secondary outcomes are to describe anxiety and depression; fear of cancer recurrence; melanoma-specific HRQoL; symptoms and...

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

Summary

ID

NL-OMON51119

Source
ToetsingOnline

Brief title
PRO-MEL study

Condition

- Other condition
- Skin neoplasms malignant and unspecified

Synonym
Quality of life

Health condition

Kwaliteit van leven

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: eigen middelen van de onderzoeksgroep

Intervention

Keyword: Immunotherapy, Melanoma, Quality of life

Outcome measures

Primary outcome

Primary outcome is to assess HRQoL. This will be assessed with The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30).

Secondary outcome

Secondary outcomes are collected through different questionnaires: sociodemographic questions, the Functional Assessment of Cancer Therapy - Melanoma (FACT-M), the Hospital Anxiety and Depression Scale (HADS), the Cancer Worry Scale (CWS), the immunotherapy-specific questtionaire, 4 questions about sexual health (EORTC sexuality module), the work-ability index (WAI) questionnaire, the 5-level EuroQoL-5D (EQ-5D-5L) and patients' perceptions of received information (QLQ-INFO25).

Study description

Background summary

Still little is known about the long term effect of the different immunotherapies on psychosocial outcomes in high risk melanoma and advanced melanoma survivors. Collecting patient-reported outcomes (PROs) and health-related quality of life (HRQoL) data is important for understanding the short term and long term impact of melanoma itself and the treatment with ICIs

on quality of life outcomes in melanoma patients. Therefore, in this study we want to do more research into patient reported outcomes, what is necessary to identify personal care needs and contribute to the development of appropriate supportive care to optimize melanoma patients* wellbeing and HRQoL.

Study objective

Primary outcome is to assess HRQoL in high risk and advanced melanoma patients treated with immune checkpoint-inhibitors. Secondary outcomes are to describe anxiety and depression; fear of cancer recurrence; melanoma-specific HRQoL; symptoms and work ability in high risk and advanced melanoma patients treated with immune checkpoint-inhibitors.

Study design

This is a prospectively enrolling, monocenter cohort study in melanoma patients eligible for undergoing ICI treatment. Study outcomes will be obtained via PRO questionnaires, to identify the short term (during treatment) and long term impact of melanoma itself and the treatment with ICIs on quality of life outcomes in melanoma patients outside clinical trial context. All PRO questionnaires will be combined into one set and administered (digitally through the local hospital platform or on paper) on several times (11 times in total) during a total follow-up of 5 years. Clinical data will be combined with the questionnaire results.

Study burden and risks

The burden for filling in each questionnaires will be maximum 30 minutes. This will be done 11 times over 60 months. The total burden for the patient over 5 years is 330 minutes (5.5 hours). There are no risks associated with participation, nor are there any additional benefits.

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

Adults of 18 years and older; Melanoma patients indicated to receive treatment with immune checkpoint-inhibitors, according to the clinical guidelines; Written informed consent to participate in the study.

Exclusion criteria

Insufficient understanding of the Dutch or English language; Inclusion in experimental clinical trials

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-04-2021
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-11-2021
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	NL75996.031.20