Patient reported outcomes in high risk and advanced melanoma patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20229

Source
NTR

Brief title
PRO-MEL

Health condition

High-risk (resectable stage III) or advanced (stage IV and unresectable stage III) melanoma

Sponsors and support

Primary sponsor: None, investigator initiated
Source(s) of monetary or material Support: Investigator initiated

Intervention

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 prospectively enrolling, monocenter cohort study in melanoma patients eligible for undergoing ICI treatment, 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 outcomes will be obtained via PRO questionnaires. Primary outcome is to assess short- and long-term HRQoL in high risk and advanced melanoma patients treated with immune checkpoint-inhibitors. Secondary outcomes are to describe short- and long-term 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 objective

No hypothesis due to the explorative character of the study

Study design

11 questionnaires distributed over 5 years (baseline, first year FU every 3 months, year two and three of FU every 6 months, year four and five of FU yearly.

Intervention

N/A

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	27-05-2021
Application type:	First submission

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
NTR-new	NL9498
Other	METC Stichting Nederlands Kanker Instituut - Het Antoni van Leeuwenhoek Ziekenhuis : METCP20MEL

Study results