Quality of life research among melanoma patients that have been treated with immunotherapy, or targeted therapy and/or surgery

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This study will evaluate Health-Related Quality of Life (general and disease specific), socio-demographic data, anxiety, depression, fear for cancer recurrence, immunotherapy related discomforts, sexual health, social functioning (work ability),...

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

Summary

ID

NL-OMON55207

Source
ToetsingOnline

Brief title
AILEEN 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 onderzoeksgroep

Intervention

Keyword: Immunotherapy, Melanoma, Quality of Life, Surgery

Outcome measures

Primary outcome

The primary study parameter is Health Related Quality of Life will be assessed with the he European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-core 30 (EORTC QLQ-C30).

Secondary outcome

The secondary outcome measurements will be gained from the use of the following questionnaires: the Melanoma Subscale and Melanoma Surgery Subscale of the Functional Assessment of Cancer Therapy * Melanoma (FACT-M), five questions about sociodemographic data, the Hospital Anxiety and Depression Scale (HADS), the Cancer Worry Scale (CWS), the immunotherapy-specific questionnaire, 4 questions about sexual health (EORTC sexuality module), social functioning (work ability) will be assessed with the work-ability questionnaire, patients will describe and value their experienced health (QUALY*s) with the 5-level EuroQOL-5D (EQ-5D-5L), and cognitive functioning will be assessed with the online Amsterdam Cognition Scan (ACS).

Study description

Background summary

The introduction of checkpoint inhibitors and targeted therapy has improved clinical outcomes of stage III and IV melanoma patients substantially. These treatments have led to long-term benefit or even cure for the patients, but there is still insufficient data on the effects of these treatments on health-related quality of life (HRQoL). Therefore, in this study we will evaluate HRQoL and patients* cognitive functioning after active treatment.

Study objective

This study will evaluate Health-Related Quality of Life (general and disease specific), socio-demographic data, anxiety, depression, fear for cancer recurrence, immunotherapy related discomforts, sexual health, social functioning (work ability), description and value of personal health (Quality Adjusted Life Years; QUALY*s), and cognitive functioning in high-risk and ad-vanced melanoma patients.

Study design

Patients with high-risk (resectable stage III) melanoma treated with adjuvant immunotherapy or targeted therapy in combination with surgery or treated with surgery only and patients with advanced (stage IV and unresectable stage III) melanoma treated with immunotherapy (pembrolizumab, ipilimumab and/or nivolumab) or targeted therapy (vemurafenib+cobimentinib, dabrafenib+trametinib, encorafenib+binimetinib). The study will consist of several databases:
1) A cohort of high-risk stage III patients that never received systemic therapy, but were treated with surgery only in 2017-2019 (B16MEL cohort and patients treated off-study at the AVL)
2) A cohort of patients treated with neoadjuvant immunotherapy (and adjuvant immunotherapy or targeted therapy in case of non-response) (OpACIN-neo cohort, PRADO extension cohort)
3) A cohort of unresectable stage III and IV melanoma patients treated with nivolumab or nivolumab in combination with ipilimumab between 2017-2019.
4) A cohort of patients treated with adjuvant immunotherapy in 2019 (B16MEL cohort and patients treated off-study at the AVL).
5) A cohort of unresectable stage III and IV melanoma patients treated with BRAF+MEK inhibition between 2017-2019.
6) A cohort of patients treated with adjuvant BRAF+MEK in 2019 (B16MEL cohort and patients treated off-study at the AVL).

Patient-reported outcome measurements in form of a questionnaire will be sent

to patients.
A neuropsychological screening will be performed online. Clinical data and baseline quality of life data (if available) will be obtained from the medical records.

Study burden and risks

Patients included in this study will have to fill in one questionnaire and perform one test to determine cognitive functioning. Filling in this questionnaire will take approximately 30 minutes. Performing the cognitive functioning test can take up to 60 minutes and some of the questions might be confronting, but there are no other 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

- At least 18 years of age
- Actively treated for melanoma by use of immunotherapy, targeted therapy, surgery or a combination.
- Willing to fill in one questionnaire and perform one online cognition test.

Exclusion criteria

- Insufficient understanding of the Dutch or English language

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):	30-01-2021
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-03-2021

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-02-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-04-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-07-2022
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	NL75206.031.20