Quality of life, cognitive function, and physical fitness of patients surviving more than 2 years after immune checkpoint inhibitor therapy

Published: 24-07-2018
Last updated: 10-04-2024

Primary Objective: - to investigate health-related quality of life (HRQoL) of patients surviving 2 years or more after the first cycle of an immune checkpoint inhibitor for melanoma or NSCLC.Secondary Objectives:- to assess neurocognitive function,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Genitourinary tract disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON48886

Source
ToetsingOnline

Brief title
Quality of life and physical fitness after immune checkpoint inhibitors

Condition

- Genitourinary tract disorders NEC
- Respiratory tract neoplasms
- Skin neoplasms malignant and unspecified

Synonym
Melanoma, NSCLC en urogenital cancers

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cancer patients, Immune checkpoint inhibitor, Quality of life, Survivorship

Outcome measures

Primary outcome

Main study endpoint is health-related quality of life (HRQoL) as measured

using the EORTC Quality of life questionnaire (QLQ-C30).

Secondary outcome

Secondary study parameters are possible late effects (neurocognitive

dysfunction, endocrine disorders, dermatologic complaints, sexual disorders and

infertility, increased cardiovascular risk, and fatigue), physical fitness,

psychosocial issues related to work/education, mood disorders (anxiety and

depression), patient and treatment-related factors potentially influencing

development of late effects, well-being, and quality of life of caregivers.

Study description

Background summary

Tremendous anti-tumor effects have been achieved using immune checkpoint inhibitors for melanoma, NSCLC and urogenital cancers with long lasting responses of more than 2 years in a substantial subgroup of patients. However, we are still largely unaware of the health-related quality of life of these patients. We should carefully and thoroughly assess the long-term burden of disease and treatment toxicity. We need this information to guide follow-up and implement intervention strategies to improve quality of life.

Study objective

Primary Objective:
- to investigate health-related quality of life (HRQoL) of patients surviving 2 years or more after the first cycle of an immune checkpoint inhibitor for melanoma or NSCLC.

Secondary Objectives:
- to assess neurocognitive function, endocrine function, cardiovascular risk, physical fitness, mood disorders, sexual problems, work participation in patients surviving 2 years or more after the first cycle of immune checkpoint inhibitor;
- to assess quality of life of the caregivers of these patients.

Study design

Observational cross-sectional study.

Study burden and risks

Participation in the study will include one study visit of approximately 2.5 hours. If possible, the study visit will be combined with a regular follow-up visit. Vena puncture is the only invasive procedure, with low risk of adverse effects. Blood will be drawn after an overnight fast. To minimize the duration of the visit, patients will be offered to fill out the questionnaires at home. Individual adverse test results will be reported to a participants* treating physician (oncologist and GP) to enable treatment or follow-up as indicated. The results of the full study group will be used to guide future interventions and support for patients treated with immune checkpoint inhibitors.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patient with melanoma, NSCLC or urogenital cancers *2 years since treatment with at least one cycle of immune checkpoint inhibitor (CTLA-4 inhibitor, PD(L)-1 inhibitor, or both) within the Department of Medical Oncology or Pulmonary Oncology of the UMCG.
2. age *18 years at time of immune checkpoint inhibitor treatment
3. all previous or subsequent therapies allowed, including (brain) irradiation, surgery for metastases, chemotherapy, and targeted therapy provided stable clinical situation at time of inclusion

Exclusion criteria

1. switch of systemic therapy or local antitumor intervention (surgery, radiotherapy) during last 2 months
2. inability to understand or abide to the study protocol
3. debilitating psychiatric illness
4. previous treatment for malignancy other than melanoma (excluding non-melanoma skin cancer, cervical intra-epithelial neoplasia (CIN) or carcinoma in situ of breast)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2018
Enrollment:	195
Type:	Actual

Ethics review

Approved WMO Date:	24-07-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-07-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-12-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT03946007
CCMO	NL61831.042.18