Safe Stop Onderzoek: het eerder staken van nivolumab of pembrolizumab bij patiënten met gevorderd melanoom die goed reageren op deze behandeling

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21032

Source
NTR

Brief title
Safe Stop Trial Melanoma

Health condition

Melanoma (cutaneous)

Sponsors and support

Primary sponsor: Erasmus MC Cancer Institute
Source(s) of monetary or material Support: Health insurance companies.

Intervention

Outcome measures

Primary outcome

The primary endpoint of this study is the rate of ongoing response according to RECIST v1.1

at 24-months (from first start of treatment with PD-1 blockade).

Secondary outcome

The secondary endpoints include best overall response, duration of response after discontinuation of PD-1 blockade, the need and outcome of rechallenge with PD-1 blockade, and changes in SAE(s). After discontinuation of PD-1 blockade, changes in HRQoL (FACT-M, EuroQol EQ-5D, CWS) will be measured at different time points and compared with patients without early discontinuation of PD-1 blockade. In addition, measurements will be performed to determine the impact of treatment discontinuation on healthcare resource use, productivity losses (RUQ-M by iMTA), and hours of informal care.

Study description

Background summary

Rationale: Based on the pivotal clinical trials, PD-1 blockade with nivolumab or pembrolizumab is usually discontinued in case of disease progression, severe toxicity, or after a treatment duration of maximum 2 years. However, durable tumor responses have been observed after early discontinuation of PD-1 blockade in patients with advanced and metastatic melanoma who achieve a tumor response. In clinical practice, an increasing number of physicians discontinues treatment on an individual basis, for example at achieving complete (CR) or partial response (PR), or on patients' request. From a toxicity, economic, and patient perspective, a shorter treatment duration is obviously to be preferred, however, early discontinuation of PD-1 blockade has not been prospectively evaluated in clinical practice.

Study objective

We hypothesize that it is safe to stop first-line nivolumab or pembrolizumab at confirmed response, while improving quality of life (QoL) and reducing the use of healthcare resources, and costs.

Study design

See above

Intervention

Discontinuation of PD-1 blockade (nivolumab or pembrolizumab) at achieving confirmed CR or PR.

Contacts

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Eligibility criteria

Inclusion criteria

For final inclusion in the trial, patients need to have a confirmed CR/PR according to RECIST v1.1 using a diagnostic CT, including a diagnostic CT at baseline

A potential subject who meets the following criteria can be screened for inclusion in this study:
- age ≥ 18 year
- advanced or metastatic melanoma
- current treatment with first-line nivolumab or pembrolizumab for advanced or metastatic melanoma; previous systemic treatment, including immunotherapy, in (neo)adjuvant setting for resectable melanoma is allowed
o Please note: if one of the PD-1 blockade treatments is replaced by the other because of a reason other than progression or non-response, e.g. because of infusion-related reactions, this is still considered first-line therapy and patients are still eligible for inclusion
- documented target lesion(s) according to RECIST v1.1 on diagnostic CT at start of PD-1 blockade with nivolumab or pembrolizumab
o For patients with CR on a diagnostic CT at response evaluation, a low-dose CT (which is usually part of 18FDG-PET/CT) is allowed at baseline
o For patients with PR on a diagnostic CT at response evaluation, a low-dose CT (which is usually part of 18FDG-PET/CT) is allowed if sufficient target lesions are measurable for response evaluation according to RECIST v1.1 criteria. In this specific case, the sponsor should be consulted.
- documented tumor response evaluation every 12(+/-1) weeks according to RECIST v1.1 using a diagnostic CT as per standard practice
- presence of MRI brain for the screening of brain metastases (prior to discontinuation of PD-1 blockade)
- planned and willing to discontinue nivolumab or pembrolizumab within 6(+1) weeks after

first confirmation of CR or PR before the full period of 2 years therapy
- signed and dated informed consent form

Exclusion criteria

concomitant systemic therapies with other anti-cancer agents, e.g. BRAF-inhibitor, anti-CTLA4 (e.g. ipilimumab), or other PD-1 blockade than nivolumab or pembrolizumab

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-10-2018
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-09-2018
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	NL7293
NTR-old	NTR7502
Other	MEC-2018-114/NL65512.078.18 : EudraCT: 2018-001384-23

Study results