Administration of immune checkpoint inhibitors through an elastomeric pump. A patient preference study and cost analysis.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON54425

Source
ToetsingOnline

Brief title
Connect&Go

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
NSCLC and head and neck cancer, renal-cell cancer, Solid or hematological tumors for which Nivolumab or Pembrolizumab monotherapy have an EMA approved indication. This includes (but is not limited to) melanoma, Various forms of cancer for which Nivolumab or Pembrolizumab monotherapy are prescribed as treatment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Elastomeric pump, Health economics, Nivolumab, Oncology, Patient Preference, Patient reported outcomes, Patient Satisfaction, Pembrolizumab, RASQ

Outcome measures

Primary outcome

The primary endpoint of this study is the percentage of patients indicating an

overall preference for ICI-B or ICI-P.

Secondary outcome

- Patient satisfaction score of ICI-B and ICI-P assessed using the Rituximab

Administration Satisfaction Questionnaire (RASQ)

- The incidence of IRRs according to CTCAE v5.0.

- The incidence of infusion site extravasations according to CTCAE v5.0.

- The percentage of HCPs indicating an overall preference for either ICI-B or

ICI-P administration.

- Monetary costs of health care resources per cycle of ICI-B and ICI-P.

- The total chair time required per cycle of ICI-B and ICI-P.

- Total and task-specific HCP time required per cycle of ICI-B and ICI-P.

Study description

Background summary

Since their introduction immune checkpoint inhibitors (ICIs) have become
standard therapy in a rapidly increasing number of tumor types and settings.

However, besides the many advantages these ICIs offer, new challenges arise. They put great strains on the available treatment capacity of outpatient oncology clinics. In recent years a number of oncology monoclonal antibodies have become available as a formulation for subcutaneous (SC) injection. These SC monoclonal antibodies such as rituximab, trastuzumab and daratumumab have demonstrated to significantly reduce patient chair time, active healthcare professional (HCP) time, thereby reducing healthcare costs. In addition to these advantages, they have also shown to be patients preferred method of administration and increase patient satisfaction.

Recently in the Erasmus MC, positive experiences have been obtained with the use of elastomeric pumps during administration of chemotherapy. ICI administration through an elastomeric pump (ICI-P) could be a safe and suitable option reduce patient chair time by enabling patients to move more freely through the hospital during ICI infusion. Based on our own data it is estimated that full adoption of elastomeric pumps for ICIs could increase the capacity of our outpatient clinic for these patients by 400%. Besides these economic advantages, patients might also prefer ICI-P over ICI administration using a *classic* IV bag (ICI-B).

Therefore we shall conduct an open-label, randomized, two cohort, two-arm crossover study to investigate the patient preference and healthcare professional preference for either ICI-B or ICI-P. Parallel to this trial an observational non-interventional microcosting study shall be conducted.

Study objective

The primary objective of this study is to evaluate the patient preference for either ICI-B or ICI-P. Secondary objectives are: to assess patient satisfaction with ICI-B and ICI-P, to establish the safety of ICI-B and ICI-P to establish the healthcare professional preference for ICI-B or ICI-P, and to perform a cost analysis.

Study design

This study is a prospective, open-label, randomised, two-cohort, two-arm, crossover, patient preference study.

Intervention

Prior to the study, eligible patients have received a minimum of 2 cycles of ICI treatment without the occurrence of hypersensitivity reactions. Thereafter, eligible patients will be randomized 1:1 to receive either 2 cycles ICI-B followed by 2 cycles of ICI-P (A-B), or 2 cycles of ICI-P followed by 2 cycles of ICI-B (B-A).

Study burden and risks

Patients will be treated with Nivolumab or Pembrolizumab as standard of care. The only additional burden for patients during participation in this trial are the three questionnaires that need to be completed during the trial. The RASQ is required to be completed twice (after 2nd and 4th administration of Nivolumab/Pembrolizumab) during trial and the patient preference Questionnaire is required to be completed after the last ICI administration during the trial.

Patients will be admitted to the outpatient clinic conform standard of care and they will be randomized into two groups. Prior to the study, eligible patients have received a minimum of 2 cycles of ICI treatment without the occurrence of hypersensitivity reactions. Major risks are not expected during this study. Nonetheless, we will carefully observe all included patients, during the whole study period, conform standard of care.

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

- Age >=18 years;
- Able and willing to give written informed consent;
- Planned treatment with nivolumab or pembrolizumab monotherapy (subjects treated with nivolumab/ipilimumab combination treatment can participate in the trial on days during which they receive nivolumab monotherapy) or any other EMA approved ICI as monotherapy for any EMA approved indication and with any dose;
- Adequate Dutch language proficiency (at least proficiency level C1)
- At least 2 prior cycles of Nivolumab or Pembrolizumab therapy
- At least 4 remaining cycles of Nivolumab or Pembrolizumab monotherapy after inclusion in the study.

Exclusion criteria

Prior infusion related reactions to Nivolumab or Pembrolizumab (any grade).

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-10-2021
Enrollment:	390
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Keytruda
Generic name:	Pembrolizumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Opdivo
Generic name:	Nivolumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-09-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-03-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2021-000058-24-NL
CCMO	NL76539.078.21
Other	NL9473