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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25676

Source
Nationaal Trial Register

Brief title
Connect&Go studie

Health condition

Solid tumors for which nivolumab or pembrolizumab monotherapy has an EMA approved indication. This includes (but is not limited to) melanoma, renal-cell cancer, NSCLC and head and neck cancer.

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

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 infusion site extravasations according to CTCAE v5.0.

- The incidence of infusion related reactions 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

Significantly more patients will express an overall preference for ICI-P versus ICI-B

Study design

Baseline screening 1st cycle ICI-B/ICI-P 2nd cycle ICI-B/ICI-P 3rd cycle ICI-P/ICI-B 4th cycle ICI-P/ICI-B
Medical history X

In- / exclusion criteria X

Provide Information about the study X

Written informed consent X

Nivolumab/Pembrolizumab monotherapy X X X X

Patient satisfaction questionnaire X X

Patient preference questionnaire X

HCP preference questionnaire X

Incidence of infusion site extravasations X X X X

Incidence of infusion related reactions X X X X

Monetary costs of healthcare resources per cycle of ICI-B X X X X

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

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

Intervention

Prior to the study, eligible patients have received a minimum of 3 doses of nivolumab or pembrolizumab without the occurrence of hypersensitivity reactions. Thereafter, eligible

patients will be randomized 1:1 in group A-B or group B-A. group A-B shall receive 2 cycles ICI-B (hereafter referred to as treatment A) followed by 2 cycles of ICI-P (hereafter referred to as treatment B). Patients in group B-A shall first receive two cycles of treatment B followed by two cycles of treatment A. eligible patients shall complete a questionnaire after two cycles of treatment A and after two cycles of treatment B. All patients will receive a dose of nivolumab every four weeks (Q4W) or pembrolizumab every three weeks (Q3W) or every six weeks (Q6W).

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥18 years;

- Able and willing to give written informed consent;

- Planned treatment with Nivolumab or Pembrolizumab monotherapy (in case of Nivolumab with or without prior
treatment with Nivolumab/Ipilimumab) for any EMA approved indication and with any dose;

- Adequate Dutch language proficiency (at least proficiency level C1)

- At least 3 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 type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-08-2021
Enrollment:	390
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9473
Other	METC EMC : METC 2021-0250

Study results