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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25676

Bron
Nationaal Trial Register

Verkorte titel
Connect&Go studie

Aandoening

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.

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of this study is the percentage of patients indicating an overall preference for ICI-B or ICI-P.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-08-2021
Aantal proefpersonen:	390
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9473
Ander register	METC EMC : METC 2021-0250

Resultaten