Comprehensive ambulatory monitoring during immunotherapy in patients with advanced melanoma: a prospective trial (CAMP-IT)

Gepubliceerd: 11-02-2020 Laatst bijgewerkt: 18-08-2022

It is feasibility to collect activity data, vital signs, and PROMS using a comprehensive online monitoring platform that consists of a wearable activity monitor, digital thermometer, and smartphone-app in patients with advanced melanoma undergoing...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22326

Bron
NTR

Verkorte titel
CAMP-IT

Aandoening

melanoma

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC, Amsterdam, The Netherlands
Overige ondersteuning: BMS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

feasibility in terms of (i) participation rates, (ii) wear-time, (iii) compliance rates with in-app questionnaires and temperature measurements, and (iv) satisfaction with the platform.

Toelichting onderzoek

Achtergrond van het onderzoek

The emergence of immune checkpoint inhibitors has improved survival outcomes for patients with advanced melanoma. However, these treatment modalities are also associated with specific immune-related toxicities. These are often reversible after prompt recognition and initiation of appropriate management, but can result in severe morbidity and hamper health-related quality of life (HRQoL) if left undetected. Hence, accurate and regular monitoring of these patients is critical. Recent advances in mHealth technologies and the rapidly expanding armamentarium of wearable devices allow for real-time objective (vital signs and physical activity) data and patient-reported outcome measurement (PROMs) collection and, hence, serve this purpose. We hypothesize that collection of real-time objective data adds to the early detection of disease- and treatment-related adverse events. The primary objective of this study is to determine the feasibility of collecting real-time PROMs, vital signs, and physical activity data in advanced melanoma patients receiving immunotherapy using a comprehensive ambulatory monitoring platform (CAMP) that consists of a smartphone app, activity monitor, digital thermometer, and online dashboard for physicians. In this prospective multi-center trial, patients (n=50) with advanced melanoma, scheduled to receive immunotherapy with immune checkpoint inhibitors, and with access to a smartphone are eligible for inclusion. Consenting patients will be asked to wear a FitBit Versa 2.0 during waking hours, collect daily temperature measurements using a Withings Smart Temporal thermometer, and answer weekly toxicity questionnaires (NCI PRO-CTCAE) using the smartphone app for the duration of the study (12 weeks). Primary outcome is feasibility in terms of (i) participation rates, (ii) wear-time, (iii) compliance rates with in-app questionnaires and temperature measurements, and (iv) satisfaction with the platform. Secondary exploratory outcomes include associations between CAMP-derived parameters and clinical outcomes: performance status (PS), HRQoL (EORTC QLQ-C30), unplanned hospitalizations, adverse events, and 1-year survival outcomes. PS and HRQoL will be rated at baseline, mid-study, and end-of-study. The occurrence of disease- and treatment-related adverse events will be documented up to 12 months from baseline. Survival outcomes will be compared to a propensity score matched group from the Netherlands Cancer Registry.

Doel van het onderzoek

It is feasibility to collect activity data, vital signs, and PROMS using a comprehensive online monitoring platform that consists of a wearable activity monitor, digital thermometer, and

smartphone-app in patients with advanced melanoma undergoing immunotherapy.

Onderzoeksopzet

T0: start immunotherapy and connection to the Comprehensive online monitoring platform
T1: (+6weeks) mid-study
T2: (+12 weeks) end-of-study
T3: (+1 year)

Onderzoeksproduct en/of interventie

Comprehensive ambulatory monitoring platform

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• >18 years
• scheduled to receive immunotherapy with ipilimumab, nivolumab, or pembrolizumab
• Ambulatory without use of walking aids
• Access to device that has the capability to sync the wearable activity monitor and digital thermometer
• Proper understanding of the Dutch language

• Have an understanding, ability, and willingness to fully comply with study procedures and restrictions
• Ability to consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• History of allergy to surgical steel or elastomer/rubber
• Using a pacemaker, implantable cardiac defibrillator, neurostimulator, hearing aids, cochlear implants, or other electronic medical equipment
• Permanent or temporary changes to the skin of the wrist (e.g. tattoos, scar tissue) that might impact heart rate sensor performance
• Incapability to use digital devices

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	11-02-2020
Soort:	Eerste indiening

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	NL8827
Ander register	METC AMC : W20_254 # 20.289

Resultaten