Effecten van PRF

Gepubliceerd: 17-08-2018 Laatst bijgewerkt: 15-05-2024

Transcutaneous pulsed radiofrequency (tPRF) may affect tumor activities.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Metastasen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25071

Bron
NTR

Verkorte titel
TcPRF-17

Aandoening

- Metastasen

Aandoening

Advanced-stage colorectal, breast, prostate, or ovarian cancer no longer responding to systemic treatment

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor:	Radboud University Medical Center
Secundaire sponsoren:	springlife
Overige ondersteuning:	Radboud University Medical Center Springlife Medical B.V. Nederlandse Stichting Pijnbestrijding

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

Tumor markers

- Carcinoembryonic antigen (CEA) for colorectal cancer;

- Carcinoma antigen 15.3 (CA15.3) for breast cancer;

- Prostate-specific antigen(PSA) for prostate cancer:

- Carcinoma antigen 125 (CA125) for ovarian cancer.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Pulsed radiofrequency (PRF) is widely used for pain relief. The working mechanism is still under discussion, and the hypothesis is that PRF may affect the reactivity of immune cells. Immune cells play essential roles in tumor progression and tumor growth, and these tumor activities can be indicated by tumor markers. In this study we focus on cancer patients receiving standard palliative treatment and explore the effect of transcutaneous PRF (tPRF) on their tumor marker.

Objective: To study the effect of tPRF on a specific tumor marker in patients with advanced-stage cancer.

Study design: The proposed study is a single-centered, open-label, single-arm proof of concept study.

Study population: Patients with advanced-stage colorectal, breast, prostate, or ovarian

cancer no longer responding to systemic treatment in Radboud UMC, and no other standard oncological treatment can be applied anymore, receiving standard palliative care, with history of tumor marker responding to disease progression and previous oncological treatment, with aged ≥ 18 years old are asked to participate.

Intervention: Participating patients will be treated with tPRF for at least two times during their regular palliative-care related hospital visiting,

Main study parameters/endpoints: Tumor marker.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

• Burden: This study has a very low burden for the participants. Study visits (three to four times) are scheduled into patients' regular palliative-care related hospital visits. tPRF treatment is applied two to three times; pain intensity and quality of life are assessed in each visiting; two blood samples are taken in two separate days (during the first and the last visiting). Besides these, there is no difference compared to standard palliative treatment.

• Risks: This study has a very low risk for the participants. tPRF is a non-invasive, painless treatment. It has been used as a pain-relief procedure with no known complications or side effects.

• Benefit: It is unknown if participants can benefit from the study.

• Group relatedness: Participating patients do not get any oncologic treatment anymore and their tumor markers keep on increasing. In the meantime, these patients visit Radboud UMC regularly for consultation on palliative care.

Doel van het onderzoek

Transcutaneous pulsed radiofrequency (tPRF) may affect tumor activities.

Onderzoeksopzet

Baseline, 2 weeks, 4 weeks, 6 weeks

Onderzoeksproduct en/of interventie

Transcutaneous pulsed radiofrequency

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) ≥ 18 years of age;

2) patients with advanced-stage colorectal, breast, prostate or ovarian cancer;

3) presently no longer responding to systemic treatment, and no other standard oncological treatment can be applied anymore (i.e. a patient is strictly in a clear palliative trajectory).

4) history of tumor marker corresponding with disease progression on imaging;

5) history of tumor marker responding to previous oncological treatment;

6) patients able and willing to give written informed consent and comply with the requirement of the study protocol;

7) life expectancy at least 3 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) treatment with any cancer therapy, including but not limited to chemotherapy and radiation therapy, within 4 weeks before baseline;

2) in the use of critical measuring devices, large metal implants or active implants like a pacemaker;

3) pregnant.

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Anders

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-01-2019
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	16-08-2018
Soort:	Eerste indiening
Toetsingscommissie:	METC Oost-Nederland
	p/a Radboudumc, huispost 628,
	Postbus 9101
	6500 HB Nijmegen
	024 361 3154
	commissiemensgebondenonderzoek@radboudumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46593
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7234
NTR-old	NTR7433
CCMO	NL62615.091.17

Register	ID
OMON	NL-OMON46593

Resultaten