Radio-Immunotherapy in MAlignant Lymphoma 1

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Tumour cell disruption by radiation generates a surplus of neo-antigens that enhances the effect of immunotherapy in solid malignancies as well as malignant lymphomas. The hypothesis is that the combination of immune checkpoint inhibitors and…

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

Samenvatting

ID

NL-OMON22178

Bron
NTR

Verkorte titel
RIMAL1

Aandoening

recurrent / refractory malignant lymphomas

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none yet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Alteration / increase in interferon I and II (INF I and II) signatures in blood, measured 3 weeks after radiotherapy and after every 3 consecutive courses of immune checkpoint blockade. It

is anticipated that the addition of radiotherapy will lead to an extra / more pronounced response.

Toelichting onderzoek

Achtergrond van het onderzoek

The main objective of the study is enhancement of the immune response by radiation, and thereby treatment efficacy, in patients with recurrent / refractory malignant lymphomas treated with immune checkpoint blockade. As a measure for immune activation, interferon I and II signature alterations will be correlated with clinical response measured by [18F]FDG PET-CT scans and the amount of circulating tumour DNA (ctDNA).
Patients will be divided into 2 groups: A. 10 patients with recurrent / refractory 9p24.1 amplified malignant lymphomas and B. 10 patients with recurrent / refractory malignant lymphoma without 9p24.1 amplification. In both groups, patients are alternately assigned to treatment with immune checkpoint inhibition alone or radiation followed by immune checkpoint inhibition. In the group of patients that start with immune checkpoint inhibition alone, radiation will be implemented in the treatment at progression or insufficient response.

Doel van het onderzoek

Tumour cell disruption by radiation generates a surplus of neo-antigens that enhances the effect of immunotherapy in solid malignancies as well as malignant lymphomas. The hypothesis is that the combination of immune checkpoint inhibitors and radiation will lead to better responses and longer survival in patients with recurrent / refractory malignant lymphoma, compared with either modality given alone.

Onderzoeksopzet

3 weeks after radiotherapy. After every 3 consecutive courses of immune checkpoint blockade.

Onderzoeksproduct en/of interventie

radiation

Contactpersonen

Publiek

Radboudumc
Richard van der Maazen

06 11079632

Wetenschappelijk

Radboudumc
Richard van der Maazen

06 11079632

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- patients with refractory / recurrent malignant lymphoma eligible for immune checkpoint blockade therapy
- aged 18 – 75 year
- WHO score ≥2
- adequate organ function
- no prior treatment with checkpoint inhibitors
- no non-infectious pneumonitis requiring steroids
- not pregnant
- patients of childbearing / reproductive potential should use 2 birth control methods
- written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not fit (mentally or physically) to undergo the proposed treatment.
- Patients with connective tissue diseases (inflammatory myopathy (polymyositis and ermatomyositis), systemic lupus erythematosus, Sjögren syndrome, systemic sclerosis, antisynthetase syndrome, rheumatoid arthritis, severe psoriasis and mixed CTDs), vasculitis (granulomatosis with polyangiitis (Wegener’s granulomatosis), microscopic polyangiitis, eosinophilic granulomatosis with polyangiitis (Churg–Strauss syndrome), severe Behçet disease, Takayasu arteritis, giant cell arteritis, Buerger disease, Kawasaki disease, polyarteritis nodosa, severe immunoglobulin A (IgA) vasculitis (Henoch–Schönlein purpura), severe cutaneous vasculitis, polymyalgia rheumatica, severe cryoglobulinaemia and

undifferentiated systemic vasculitis) and other autoimmune diseases (primary biliary cirrhosis, severe autoimmune hepatitis, multiple sclerosis, severe antiphospholipid syndrome, myasthenia gravis, Guillain–Barré syndrome, inflammatory bowel disease, Miller–Fisher syndrome, Vogt–Koyanagi–Harada syndrome, eosinophilic fasciitis (Shulman syndrome), relapsing polychondritis and severe autoinflammatory diseases) (Martins et al. 2019).
- Sensory or motor peripheral neuropathy > grade 2.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	20
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

ID: 50953
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9091
CCMO	NL75774.091.21
OMON	NL-OMON50953

Resultaten