Vaccin tracking in healthy volunteers

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23478

Bron
NTR

Verkorte titel
n/a

Aandoening

Human Papilloma Virus 16
Peptide vaccin
Fluorescence
Pharmacokinetics

Ondersteuning

Primaire sponsor: Centre for Human Drug Research (CHDR)
Leiden University Medical Center (LUMC)
Overige ondersteuning: CTMM Cancer Vaccine Tracking

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Treatment-emergent (serious) adverse events ((S)AEs); concomitant medication; clinical laboratory tests (haematology, chemistry, urinalysis); vital signs (pulse rate, systolic blood pressure, diastolic blood pressure); injection site status; physical examination findings.

Toelichting onderzoek

Achtergrond van het onderzoek

Improved understanding of the immune system has led to progress in the immunotherapy of cancer. Our current peptide-based vaccination approach is very promising but requires optimization for eradication of established cancers. For further improvements of peptide vaccine strategies including adjuvant comparisons, effect of different formulations, and comparison of dosing schedules, the in vivo fate of the vaccines needs to be studied. The trafficking and metabolism of peptide vaccine antigens and the effects of dose and formulation (e.g. its pharmacokinetics; PK) are largely unknown, while this will determine the time course and extent of subsequent peptide-specific T cell responses and thus therapeutic efficacy. To gain insight in the PK of peptide vaccines a near-infrared (NIR) fluorescent dye was labelled to Human Papilloma Virus 16 peptide antigen (HPV-NIRD1). The aim of this study was to determine feasibility of obtaining PK data using optoacoustic and fluorescence imaging and to assess safety after a single subcutaneous (sc) administration of HPV-NIRD1 in healthy adult volunteers.

Doel van het onderzoek

The fate of peptide vaccine antigens and the effect of dose and formulation (e.g. its pharmacokinetics; PK) is largely unknown, while this will determine the time course and extent of subsequent peptide-specific T cell responses and thus therapeutic efficacy. To gain insight in the PK of peptide vaccines a near-infrared (NIR) fluorescent dye was labelled to Human Papilloma Virus 16 peptide antigen (HPV-NIRD1). The aim of this study was to determine feasibility of obtaining PK data using optoacoustic and fluorescence imaging and to assess safety after a single subcutaneous (sc) administration of HPV-NIRD1 in healthy adult volunteers.

Onderzoeksopzet

The total duration of the study for each subject will be up to 49 days divided as follows:

„X Screening: Up to 21 days before dosing;

„X Treatment and study assessments: Days 0 to 28

„X In Clinic period: Days 0 to 1 (single subcutaneous administration of HPV-NIRD1 on day 0)
„X Follow-up visit: 2,3,7, and 28 days after dose administration.

Onderzoeksproduct en/of interventie

HPV-NIRD1 contains HPV-16 E6 peptide 71-95 conjugated to Near-Infrared Dye 1 and has been manufactured at the Interdivisional GMP Facility LUMC (IGFL) of the department of Clinical Pharmacy and Toxicology, LUMC.

Study drug HPV-NIRD1 will be administered as a single subcutaneous injection. Two strengths of HPV-NIRD1 will be administered: 80ug, which corresponds to 60 ug of the HPV peptide and 20 ug NIRD1 label and 400ug which corresponds to 300 ug HPV peptide and 100 ug NIRD1 label.
Indocyanine green (ICG) will be used as a comparative drug for this study.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. The subject is 18-65 years old at screening.

2. The subject is able and willing to comply with study procedures, and signed and dated informed consent is obtained before any study-related procedure is performed.

3. Female subjects need to be either surgically sterile, post-menopausal or pre-menopausal with a negative urine pregnancy test at screening and just before administration of HPV-NIRD1.Pre-menopausal female subjects who are not surgically sterile should also employ an effective method of birth control for at least three months post dosing.

4. The subject¡¦s body mass index is 18-22 kg/m2.

5. The subject has a normal or clinically acceptable medical history, physical examination, and
vital signs findings at screening (within 21 days before administration of study drug).

6. The subject¡¦s screening ECG and clinical laboratory test results are within normal limits, or if
any are outside of normal limits they are considered to be clinically insignificant.

7. The subject has negative screening test results for hepatitis B, hepatitis C, and human immunodeficiency virus.

8. The subject has negative test results for drug and alcohol screening.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The subjects uses prescription drugs or OTC-drugs that may have an impact on the study objectives.

2. Previous exposure to the investigational drug.

3. Participation in a clinical trial within 90 days of screening or more than 4 times in the previous year.

4. Known hypersensitivity to the investigational drug or comparative drug or drugs of the same class, or any of their excipients.

5. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or interpretation of the results such as drug or alcohol dependence or psychiatric disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-05-2016
Aantal proefpersonen:	6
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-07-2016
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	NL5832
NTR-old	NTR5987
Ander register	P15.322 : CHDR1507

Resultaten