Vaccin tracking in healthy volunteers

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23478

Source
NTR

Brief title
n/a

Health condition

Human Papilloma Virus 16
Peptide vaccin
Fluorescence
Pharmacokinetics

Sponsors and support

Primary sponsor: Centre for Human Drug Research (CHDR)
Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: CTMM Cancer Vaccine Tracking

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The following endpoints will be determined for HPV-NIRD1 following administration, they will be derived by imaging of injection site and draining inguinal lymph nodes:
„X Absolute fluorescent signal of injection site or draining inguinal lymph node at different time points and doses
„X SBR (signal to background ratio), defined as fluorescent signal of injection site or draining inguinal lymph node compared to fluorescence signal of tissue surrounding the injection side or lymph node, at different time points and doses.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2016
Enrollment:	6
Type:	Actual

Ethics review

Positive opinion

Date:	20-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5832
NTR-old	NTR5987
Other	P15.322 : CHDR1507

Study results