Study for intraoperative imaging of prostate cancer using OTL78

Gepubliceerd: 24-04-2020 Laatst bijgewerkt: 15-05-2024

OTL78 is safe for use in healthy male individuals and patients with prostate cancer. OTL78 binds to malignant prostate tissue and malignant lymph nodes.

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

Samenvatting

ID

NL-OMON21822

Bron
NTR

Verkorte titel
CHDR1849

Aandoening

Prostate cancer

Ondersteuning

Primaire sponsor: On Target Laboratories, Inc
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Part A: healthy volunteers (n= up to 15)
Primary/safety objective:

- To assess the safety, tolerability and pharmacokinetics of a single IV dose of OTL78

Part B/part C: patients (n= up to 24)
Primary/safety objective:
- To assess the safety, tolerability and pharmacokinetics of a single IV dose of OTL78

Toelichting onderzoek

Achtergrond van het onderzoek

Surgery is the mainstay in the initial treatment of many solid tumors. Complete resection has shown to be an important prognostic indicator for survival. However, this can be challenging when the surgical field is observed with the naked eye only. Therefore, agents that improve tumor identification and the likelihood of complete resection are being developed. These agents are directed towards tumor-specific targets and emit light at non-visible wavelengths. By using near-infrared (NIR) camera systems, they may enable detection of malignant tissues and distinguish them from normal tissue. OTL78 is an imaging agent that specifically binds to the PSMA (prostate specific membrane antigen) which is expressed on prostate cells, particularly cancer and possibly involved lymph nodes. Intra-operative identification of cancer tissue using real-time imaging modalities that could improve tumor identification and demarcation would provide a very useful tool to reduce the frequency of positive resection margins and increase complete removal of locally spread tumor and involved lymph nodes. Complete removal of cancer and metastases may in turn reduce rates of re- interventions and therefore morbidity to help improve patient outcomes. As there is no clinical experience with OTL78, the study drug will first be studied in healthy volunteers and subsequently in patients to assess the safety, tolerability and pharmacokinetics The performance of OTL78 in intraoperative imaging of prostate cancer will be assessed in (Part B/part C, proof of concept).

Doel van het onderzoek

OTL78 is safe for use in healthy male individuals and patients with prostate cancer. OTL78 binds to malignant prostate tissue and malignant lymph nodes.

Onderzoeksopzet

-60 Days till EOS

Onderzoeksproduct en/of interventie

OTL78

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Part A (healthy volunteers)
Ten (n=10) healthy volunteers will take part in this study (maximum=15 if a 3rd dosing cohort is added).
Inclusion criteria
1) Male and 18-65 years old at screening.
2) Able and willing to comply with study procedures, with signed and dated informed consent obtained before any study-related procedures are performed.
3) Agree to use an effective method of contraception for 90 days after administration.
4) A body mass index is ≤30 kg/m2.
5) The subject is healthy with no acute or chronic medical illnesses, has a normal physical examination, and normal vital signs findings at screening.
6) The subject’s screening 12-lead ECG and clinical laboratory test results are within normal limits, or if any are outside of normal limits they are considered clinically insignificant at the discretion of the investigator.
7) Negative screening test results for hepatitis B, hepatitis C, and human immunodeficiency virus.
8) Negative test results for drug and alcohol screening.
9) Absence of any psychological, familial, sociological or geographical condition that at the discretion of the investigator could potentially hamper compliance with the study protocol and follow-up schedule, such conditions

Part B
The study will be performed in maximum 6 patients.
Inclusion criteria
1) Male patients > 18 years of age and older at screening.
2) Able and willing to comply with study procedures, and signed and dated informed consent obtained before any study-related procedures are performed.
3) Known or high clinical suspicion of (primary or recurrent) prostate cancer scheduled to undergo a pelvic lymph node dissection for salvage or staging at the LUMC.
4) The 12-lead ECG and clinical laboratory test results are within normal limits, or if any are outside of normal limits they are considered clinically insignificant at the discretion of the investigator
5) Chronic or acute medical illness that in the discretion of the investigator may confound or complicate the findings in this study
6) Patients are clinically fit for surgery
7) Agree to use an effective method of contraception for 90 days after administration
8) Absence of psychological familial, sociological or geographical condition that at the discretion of the investigator could potentially hamper compliance with the study protocol and follow- up schedule; such conditions should be discussed with the patient during the prescreening period.

Part C
The study will be performed in maximum 18 patients.
Inclusion criteria
1) Male patients > 18 years of age and older at screening.
2) Able and willing to comply with study procedures, and signed and dated informed consent obtained before any study-related procedures are performed.
3) Known or high clinical suspicion of prostate cancer (Gleason score 7+) planned for a prostatectomy at the NKI.
4) The 12-lead ECG and clinical laboratory test results are within normal limits, or if any are outside of normal limits they are considered clinically insignificant at the discretion of the investigator
5) Chronic or acute medical illness that in the discretion of the investigator may confound or complicate the findings in this study
6) Patients are clinically fit for surgery
7) Agree to use an effective method of contraception for 90 days after administration
8) Absence of psychological familial, sociological or geographical condition that at the discretion of the investigator could potentially hamper compliance with the study protocol and follow- up schedule; such conditions should be discussed with the patient during the prescreening period.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Part A
Healthy volunteers (phase 1 a/1 b)

1) Female subjects
2) Known acute or chronic disease, abnormal physical examination or blood tests of clinical significance.
3) The subject has previously been included in an OTL study.
4) Use of prescription drugs within 30 days of screening and during study participation
5) Participation in a clinical trial within 90 days of screening or more than 4 times in the previous year.
6) History of clinically significant allergies or anaphylactic reactions.
7) History of allergy to any of the components of OTL78 or excipients (see Investigator's Brochure).

Part B / Part C
Patients will be excluded if any of the criteria below apply:
1) Any condition that in the opinion of the investigators could potentially jeopardize the health status of the patient
2) History of clinically significant allergies or anaphylactic reactions
3) History of allergy to any of the components of OTL78 or excipients
4) Impaired renal function defined as eGFR<50 ml/min/1.73m2
5) Impaired liver function defined as values greater than 3x the upper limit of normal (ULN) for ALT, AST, or 2x the upper limit of normal for total bilirubin (unless due to Gilbert Syndrome)
6) Previous participation in an OTL study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-07-2019
Aantal proefpersonen:	39
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	24-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49366
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8552
CCMO	NL70379.056.19
OMON	NL-OMON49366

Resultaten

Samenvatting resultaten
N.A.