Clinical study to evaluate the safety and efficacy of recMAGE-A3 in patients from which the bladder is removed due to muscle invasive bladder cancer.

Gepubliceerd: 11-04-2011 Laatst bijgewerkt: 18-08-2022

The disease free survival will be prolonged in MAGE-A3 positive patients treated with recMAGE-A3.

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

Samenvatting

ID

NL-OMON28470

Bron
Nationaal Trial Register

Verkorte titel
MAGNOLIA

Aandoening

Muscle invasive bladder cancer, radical cystectomy

Ondersteuning

Primaire sponsor: EAU Research Foundation, Arnhem, The Netherlands
Overige ondersteuning: GSK BIO, Belgium

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Evaluation of the clinical efficacy in terms of Disease Free Survival of treatment versus placebo in patients with bladder cancer with MAGE-A3 expression after cystectomy.

Toelichting onderzoek

Achtergrond van het onderzoek

Proof-of-Concept for activity was reached in a double-blind, randomized, placebo-controlled Phase II in NSCLC. A second Proof-of-Concept was obtained indepently in a Phase II study in metastatic melanoma. The data to date suggest that the investigational MAGE-A3 ASCI is well-tolerated..

Since MAGE-A3 tumour antigen is expressed in approximately 40% of patients with bladder cancer, the possibility that recMAGE-A3 may also be an efficient therapy in patients with bladder cancer needs to be explored.

Doel van het onderzoek

The disease free survival will be prolonged in MAGE-A3 positive patients treated with recMAGE-A3.

Onderzoeksopzet

FPI: August 2011;

LPFV: July 2013;

LPLV: November 2016.

Onderzoeksproduct en/of interventie

Patients will be randomized for recMAGE-A3 + AS15 or placebo on 2:1 ratio. 5 doses will be administered at 3-week intervals followed by 8 doses administered at 3-month intervals for a total maximum duration of study treatment administration of 27 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Aged >= 18 years, either sex;

2. Histologically confirmed MAGE-A3 positive;

3. Written informed consent has been obtained prior to any protocol-specific procedure;

4. TNM classification of surgically removed specimen: Stage T2,3 N0 or N1 or N2 and M0 or Stage T4 N0 M0;

5. No residual disease/metastasis max 9 weeks prior to randomization;

6. Patient is fully recovered from surgery within 9 weeks following cystectomy;

7. Adequate bone-marrow reserve, renal function and hepatic function;

8. WHO performance status 0 – 1 at the time of randomization;

9. Female patients must be of non-childbearing potential or must practice adequate contraception.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous/concomitant malignancies at other sites;

2. Any anti-cancer treatment;

3. Radiotherapy of the abdominal or pelvic region, within 6 months prior to randomization;

4. Women who are pregnant or breast feeding;

5. Known infection with human immunodeficiency virus (HIV) or chronic hepatitis B or C;

6. History of allergic reactions likely to be exacerbated by the study investigational product;

7. Immunosuppressive or immunodeficient condition or potential immune-mediated disease (vitiligo excl.);

8. Patient has received a major organ allograft;

9. Concomitant treatment with systemic corticosteroids /immunosuppressive agents;

10. Investigational or non-registered medicinal products other than the study medication;

11. Psychiatric/addictive disorders compromising the ability to comply with the study procedures;

12. Other medical problems that limit compliance with the study/expose the patient to unacceptable risk;

13. The patient uses alternative treatments eg. plantextracts.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt

(Verwachte) startdatum:	30-06-2011
Aantal proefpersonen:	273
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	11-04-2011
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	NL2708
NTR-old	NTR2846
Ander register	EAU-RF : 2010-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A