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.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28470

Source
Nationaal Trial Register

Brief title
MAGNOLIA

Health condition

Muscle invasive bladder cancer, radical cystectomy

Sponsors and support

Primary sponsor: EAU Research Foundation, Arnhem, The Netherlands
Source(s) of monetary or material Support: GSK BIO, Belgium

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Overall survival;

2. Disease-free specific survival (DFSS);

3. Distant metastasis-free survival (DMFS);

4. Safety of recMAGE-A3 + AS15 ASCI;

5. Immune response to recMAGE-A3 + AS15 ASCI;

6. Translational research on gene signature and expression.

Study description

Background summary

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.

Study objective

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

Study design

FPI: August 2011;

LPFV: July 2013;

LPLV: November 2016.

Intervention

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.

Contacts

Public
EAU Research Foundation
Raymond Schipper
[default]
The Netherlands
+31263890677
Scientific
EAU Research Foundation
Raymond Schipper
[default]
The Netherlands
+31263890677

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	30-06-2011
Enrollment:	273
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-04-2011
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	NL2708
NTR-old	NTR2846
Other	EAU-RF : 2010-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A