SAKK 06/14. A phase I/II open label clinical trial assessing safety and efficacy of intravesical instillation of VPM1002BC in patients with recurrent non-muscle invasive bladder cancer after standard BCG therapy

Published: 11-08-2016
Last updated: 30-01-2025

The objective of the trial is to determine safety, tolerability and efficacy of VPM1002BC, in order to establish this medication as a therapy for non-muscle invasive bladder cancer in the future.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON45818

Source
ToetsingOnline

Brief title
VPM1002BC in recurrent non-muscle invasive bladder cancer

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
bladder cancer, recurrent non-muscle invasive bladder cancer

Research involving

Human

Sponsors and support

Primary sponsor: Swiss Group for Clinical cancer Research
Source(s) of monetary or material Support: Serum Institute of India;Pvt. Ltd.,Swiss Group for clinical cancer research

Intervention

Keyword: BCG therapy, bladder cancer, recurrent non-muscle invasive bladder cancer, VPM1002BC

Outcome measures

Primary outcome

Phase I: Dose limiting toxicity of intravesical VPM1002BC instillations

Phase II: Recurrence-free rate in the bladder at 60 weeks

Secondary outcome

Time to recurrence in the bladder

Time to recurrence

Time to progression

Overall survival

Adverse events

Tolerability

Quality of Life

Study description

Background summary

For patients with recurrence of a non-muscle invasive bladder cancer after BCG therapy, the current guidelines recommend cystectomy as the oncologically safest therapy option, and a second course of BCG therapy as a possibility for

bladder sparing. Whilst for the bladder sparing therapy, retrospective studies describe a response to second BCG therapy in up to 50 % of patients, recent prospective studies show significantly poorer responses. There are only few therapy options for patients not willing to have cystectomy or not fit enough for the operation. With the genetically modified VPM1002BC, an innovative immunotherapy with very good immunogenicity and safety in preclinical studies is offered to this group of patients.

Study objective

The objective of the trial is to determine safety, tolerability and efficacy of VPM1002BC, in order to establish this medication as a therapy for non-muscle invasive bladder cancer in the future.

Study design

Multicenter, open label, single arm, phase I/II trial

Intervention

Induction: 6 intravesical instillations of VPM1002BC in 6-12 weeks
Maintenance: 3 instillations of VPM1002BC at months 3, 6 and 12

Study burden and risks

In view of the documented risks, and in view of the overall potential benefit for patients suffering from recurrent NMIBC, the benefit-risk-balance for this study is considered to be acceptable. The identified risks associated with VPM1002BC treatment are the one expected in conventional BCG treatment but in milder form such as infection and infestation (cystitis and inflammatory reaction), fever, flu-like symptoms including malaise, fever, chills, general discomfort, nausea, frequent urination with discomfort and pain and in man asymptomatic granulomatous prostatitis. Some adverse events can be anticipated so that a mitigation of the risks can be performed.
Of note, based on the recombinant and less virulent nature of VPM1002BC as compared to routine BCG strains, the sponsor anticipates a considerably improved safety profile, a factor of key importance in settings with elderly patients, for whom a chemotherapy is normally not indicated due to other co-morbidities and high anesthesiological risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Histologically confirmed diagnosis of recurrent NMIBC
Negative cytology (except for CIS)
Planned treatment starts 2-6 weeks after last TURB
One previous cycle of intravesical BCG (induction phase with at least 5 instillations) not more than 5 years ago for NMIBC
Recurrent high-risk NMIBC for progression

Exclusion criteria

Stress urinary incontinence >I°, urge urinary incontinence
Active concomitant malignant conditions
Primary or secondary immunodeficiencies
Positive HIV test
Chronic administration of immunosuppressive drugs
Uncontrollable urinary tract infection

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-09-2016
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Genetic modified organism

Ethics review

Approved WMO Date:	11-08-2016
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-12-2016
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	31-08-2017

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-09-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-02-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	05-03-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2014-005330-58-NL
ClinicalTrials.gov	NCT02371447
CCMO	NL58065.000.16