A phase I-II open label clinical trial, evaluating the efficacy and safety of administration of the therapeutic vaccine PEP-223/CoVaccine HT, to hormone treatment naive, immunocompetent subjects with T1-3, N0-1/x, M0 prostate cancer, eligible for hormone therapy.

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primary aim of the study To investigate the efficacy of PEP-223/CoVaccine HT in decreasing serum testosterone levels to below castrate levels, i.e. to < 2 nmol/l, within 8 weeks after the last of three injectionssecondary aims of the studyTo...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON35662

Source
ToetsingOnline

Brief title
PEP223-NL-701

Condition

- Reproductive neoplasms female malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym

prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Pepscan Therapeutics B.V.
Source(s) of monetary or material Support: Pepscan Therapeutics B.V.

Intervention

Keyword: hormone therapy, prostate cancer, therapeutic vaccin

Outcome measures

Primary outcome

Primary efficacy parameter: serum testosterone levels

Secondary outcome

Secondary efficacy parameters:

- serum FSH levels, serum LH levels and serum anti-GnRH Ab levels.

Safety parameters:

- (spontaneous) reports of adverse events

- laboratory data (endocrinology, hematology, biochemistry) and urinalysis

- ECG

- blood pressures, pulse rate, respiratory rate, body temperature

- Physical examination

- serum PSA levels

Study description

Background summary

GnRH is a hormone that is produced by (part of) the brain. It stimulates a

certain gland to produce another hormone that stimulates the testes to produce testosterone. The drugs used to date to stop the production of the male hormone, testosterone, are the so-called GnRH (or LHRH) analogues. By continuously administering these analogues, the gland that produces the stimulating hormone becomes insensitive en doesn*t produce this hormone any more. As a result, the testes aren*t stimulated any more to produce testosterone and the testosterone blood levels decrease. A disadvantage of this treatment modality is that the drug has to be administered continuously to become and stay effective. The new drug that is investigated in the present study, may offer an alternative treatment modality and could be more effective in decreasing the tumor or inhibition of its growth than other hormone therapies.

Study objective

primary aim of the study
To investigate the efficacy of PEP-223/CoVaccine HT in decreasing serum testosterone levels to below castrate levels, i.e. to < 2 nmol/l, within 8 weeks after the last of three injections

secondary aims of the study
To investigate:
- the time course of testosterone suppression induced by PEP-223/CoVaccine HT
- the efficacy of PEP-223/CoVaccine HT in decreasing serum FSH and LH levels
- the antibody response to PEP-223/CoVaccine HT
- the safety and tolerability of PEP-223/CoVaccine HT

Study design

This is an open label phase I-II study in which eligible subjects will receive three injections with the therapeutic vaccine PEP-223 on days 0 (primer), 14 and 28 (boosters), followed by an observation period of 8 weeks. PEP-223 will be administered with the adjuvant CoVaccine HT. The total study duration for an individual patient is 12 weeks.

Intervention

Three adminstrations (2 weeks apart) of 7 µg conjugated modified GnRH peptide (PEP-223) in 2 ml of total vaccine (containing 0,5 ml adjuvant). This is to be administrated as as 2 x 1 ml IM injections in the right and left upper leg, gluteal or deltoid muscle.

Study burden and risks

The patient is asked to come to the hospital for 8 visits in 13 weeks time. The vaccine will be administrated on three different occasions (2 weeks in

between) by means of two intramusculair injections per occasion. After the administration of the injections the patient is kept for observation for 4 hours in the hospital.
Blood sampling takes place at each of the 8 visits. The amount of blood taken per visit differs but in total not more than 225 ml will be taken.
At 6 visits, blood pressure, pulse, respiratory rate and temperature are measured
At 6 visits an ECG is made and the patient will undergo a physical examination.
At 5 visits the patient must bring a urine sample.
Three times, the patient will be asked to keep a diary for 1 week long to record possible reactions to the injections and to record twice daily the measured temperature.

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

1 pathological confirmed prostatic adenocarcinoma, clinical stage (c) cT1-3, cN0-1/x, cM0;
2 baseline testosterone levels of > 4 nmol/l;
3 baseline PSA level of > 10 µg/l;
4 eligible for hormone therapy;
5 willingness to comply with the protocol conditions and procedures;
6 willing and able to give informed consent.

Exclusion criteria

1 clinical evidence of distant metastases;
2 previous (within 3 years before enrolment into the present study)hormonal therapy administered specifically for prostatic carcinoma;
3 development of another invasive neoplastic disease during the previous 5 years, or concomitant presence of another invasive neoplastic disease, except basal cell carcinoma or squamous cell carcinoma of the skin;
4 primary or secondary immunodeficiency, including immunosuppressive disease or use of corticosteroids or other immunosuppressive medications;
5 concomitant administration -or administration during the 12 weeks preceding study inclusion- of immune enhancing medication or testosterone supplements;
6 presence of bacterial prostatitis causing a PSA increase during the 8 weeks preceding study inclusion;
7 simultaneous participation in another clinical trial or participation in a clinical trial involving investigational drugs within 3 months before enrolment into the present study;
8 BMI > 30 kg/m2;
9 a previous serious reaction to a vaccine such as angioedema or anaphylaxis.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2008
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	PEP-223/CoVaccine HT

Ethics review

Approved WMO Date:	04-06-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-08-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-04-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-11-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-03-2010
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-04-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	03-05-2010
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	EUCTR2007-005316-80-NL
CCMO	NL20226.000.07