Vaccination against prostate cancer

Submission date 06/10/2016	Recruitment status No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/10/2016	Overall study status Completed	 Statistical analysis plan Results
Last Edited 20/01/2017	Condition category Cancer	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

The prostate is a small gland in the pelvis found only in men. Prostate cancer is one of the most common cancers in men. Most cases of prostate cancer occur in patients over the age of 50 and currently there is no cure for it. The treatments mostly rely on chemotherapy to kill cancer cells, but they can cause unpleasant side effects. A vaccine has been developed to stimulate the patient's immune system to attack the cancer cells and shrink the tumour. The aims of this study are to see how safe the vaccine is, whether it can restrict the growth of prostate cancer tumours and also whether it can lead to an increase in patients' life expectancy.

Who can participate? Men aged 50-90 with prostate cancer

What does the study involve?

Participants are examined by a doctor a day before the first vaccination. Overall mental health, blood pressure, and pre-existing diseases are recorded and routine blood and urine tests are conducted. Participants are vaccinated five times with five different vaccine doses over 29 days. Weekly physical examinations and blood and urine tests are also conducted over the month. Afterwards, participants are monitored monthly for a total of 11 months. They are examined throughout the study to find out about any possible side effects of the vaccine. In addition, they are monitored to investigate any positive results from the treatment such as shrinkage of the tumor.

What are the possible benefits and risks of participating?

Participants are expected to have an immune response against the prostate tumor, which should decrease tumor growth and even shrink the tumor size. However, this vaccination could be accompanied with side effects that are generally seen with other types of vaccination. Pain, swelling and redness in the injection site are expected. Flu-like symptoms such as fever, muscle and joint pain, headache and fatigue could be experienced by the participants.

Where is the study run from?

- 1. Golestan Hospital (Iran)
- 2. Mehr Hospital (Iran)
- 3. Taleghani Hospital (Iran)
- 4. Arya Hospital (Iran)

When is the study starting and how long is it expected to run for? October 2016 to October 2019

Who is funding the study? Ministry of Health and Medical Education (Iran)

Who is the main contact? Dr Elham Allahbahshi

Contact information

Type(s) Scientific

Contact name Dr Elham Allahbahshi

Contact details Ahvaz Jundishapur University of Medical Sciences Ahvaz Iran 61357-15794

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers U-86135

Study information

Scientific Title

Evaluating the safety and tolerability of intravenous administration of an RNA-lipoplex cancer vaccine targeting three tumor-associated antigens in patients with prostate cancer

Study objectives

Vaccination of prostate cancer patients with RNA-lipoplex for expression of PAP, PSMA, and STEAP1 inhibits the growth of prostate tumors and significantly enhances the life expectancy of the patients.

Ethics approval required Old ethics approval format

Ethics approval(s)

Ethics committee of the Ahvaz Jundishapur University of Medical Sciences, 17/08/2016 , ref: EC20160712-3

Study design Multicentre interventional study

Primary study design Interventional

Secondary study design

Study setting(s) Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Weekly (4-6 doses) intravenous administration of RNA-lipoplex for expression of three prostate cancer antigens (PAP, PSMA, STEAP1). RNA-lipoplex vaccine will be administrated intravenously. The patients will be vaccinated 5 times for the total of 29 days using the following doses: Day 1: 7.5 ug RNA-lipoplex Day 8: 15 ug RNA-lipoplex Day 15: 30 ug RNA-lipoplex Day 22: 30 ug RNA-lipoplex Day 29: 30 ug RNA-lipoplex

The patients will be examined by a physician a day before the first vaccination. Overall mental health, blood pressure, and pre-existing diseases will be examined and recorded. Routine blood and urine tests will be conducted before the first vaccination. Weekly physical exams and blood and urine tests will be conducted for the total of 1 month. Afterwards, the patients will be monitored monthly for the total of 11 months.

Peripheral blood will be collected before vaccination and in week 1, week 2, week 3, week 4, month 2, month 3 of post-vaccination. Using the collected blood samples, specific T cell response and interferon production will be measured by ELISPOT. Using the same blood samples, specific antibody response and the total free PSA will also be measured by ELISA.

Intervention Type

Biological/Vaccine

Primary outcome measure

- 1. Number of adverse events as a measure of safety and tolerability over 90 days
- 2. Total number of adverse events over 90 days
- 3. Number of patients with adverse events over 90 days

Secondary outcome measures

1. Change of induced T-cell responses for RNA-Lipoplex vaccine from visit 2 (day 1) to day 90, assessed by immunoassays

Vaccine-induced T-cell responses in peripheral blood assessed by immunoassays before vaccination and in week 1, week 2, week 3, week 4, month 2, month 3 of post-vaccination
 Vaccine-induced antibody responses in peripheral blood assessed by immunoassays before vaccination and in week 1, week 2, week 3, week 4, month 2, month 3 of post-vaccination
 Change in serum PSA (prostate specific antigen) assessed by immunoassays before vaccination and in week 1, week 2, week 3, week 4, month 2, month 3 of post-vaccination
 Change in serum PSA (prostate specific antigen) assessed by immunoassays before vaccination and in week 1, week 2, week 3, week 4, month 2, month 3 of post-vaccination
 Change in the size of tumor. Patients' tumors will be scanned using MRI and PET/CT before the vaccination and after 3 months. This may be repeated for certain patients after 1 year, depending on the response to the treatment.

Overall study start date

15/10/2016

Completion date

14/10/2019

Eligibility

Key inclusion criteria 1. Male patients with prostate cancer 2. Age 50-90 years old

Participant type(s) Patient

Age group Mixed

Sex Male

Target number of participants 30

Key exclusion criteria Unconfirmed cases of prostate cancer

Date of first enrolment 15/10/2016

Date of final enrolment 14/10/2018

Locations

Countries of recruitment Iran

Study participating centre Golestan Hospital Ahwaz Khuzestan Iran 61357-15794

Study participating centre Mehr Hospital Tehran Province District 6

W Zartosht St Tehran Iran 61357-15794

Study participating centre Taleghani Hospital Tabnak St Velenjak Region Chamran High Way Tehran Iran 61357-15794

Study participating centre Arya Hospital

Keshavarz Blvd Vesal Shirazi St. 10000 Tehran Iran 61357-15794

Sponsor information

Organisation Ahvaz Jundishapur University of Medical Sciences

Sponsor details

Golestan Blv Ahvaz Iran 61357-15794

Sponsor type University/education

ROR https://ror.org/01rws6r75

Funder(s)

Funder type Government

Funder Name Ministry of Health and Medical Education

Alternative Name(s) MOHME

Funding Body Type Government organisation

Funding Body Subtype National government

Location Iran

Results and Publications

Publication and dissemination plan To be confirmed at a later date

Intention to publish date 14/10/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Elham Allahbahshi

IPD sharing plan summary Available on request