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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
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
1. Change of induced T-cell responses for RNA-Lipoplex vaccine from visit 2 (day 1) to day 90, assessed by immunoassays
2. 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
3. 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
4. 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
5. 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.

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
Male

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

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

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