

Clinical and Laboratory Aspects of a Phase II Clinical Trial of a Prostate Cancer Vaccine and Shadowing experience in the Field of Urology

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Goals

- To observe and participate in the clinical and laboratory aspects of a Phase II Clinical trial of an adenosine/PSA vaccine for the treatment of prostate cancer in patients with recurrent disease.
- To observe and shadow various surgeries and radiation treatment that the patients have gone through before getting into the trial and to also observe other urological surgeries and treatment to expand my knowledge and understanding of the field and the anatomy and physiology of the male reproductive organ and urinary tract

Background

- A replication-deficient adenovirus was transformed with the gene for human PSA producing the Ad/PSA vaccine.
- Results of our prior Phase I trial of the Ad/PSA vaccine demonstrated its safety and ability to induce anti-PSA immune response in 68% of patients
- The Phase II trial is designed to determine whether the vaccine has an effect on the responses to PSA and to prostate cancer cells
- The Phase II clinical trial is governed by two protocols. Protocol 1 consists of patients with prostate cancer recurrence following surgery or radiation. Protocol 2 consists of patients who have experienced hormone refractory prostate cancer.

Procedures

PROTOCOL 1 (14 individuals)

- Patients with prostate cancer recurrence following surgery or radiation
- Arm A: patients receive vaccine alone; 3 injections, 1 month apart
- Arm B patients: 14 days of hormone therapy, followed by the vaccine, 3 injections one month apart.

PROTOCOL 2 (12 individuals)

- Hormone refractory prostate cancer
- Single arm: Vaccine only, 3 injections 1 month apart

CLINICAL AND LABORATORY EXPERIENCE

- Observe and participate in surgeries and treatment of patients who have prostate cancer and other urologic surgeries.
- Collect blood from patients and process it in the laboratory separating the serum, plasma and lymphocytes. The Eli spot assay is also performed.

Results

Clinical Trial Patients

- Weekly lab meetings are held with the Principal investigator, basic scientist, urologist, medical oncologist, nurse practitioner, physician's assistant and clinical trial board to review enrolled patients and discuss outcomes of their follow-up visits. Also engage in discussions about the recruitment of possible new patients for the trial.

Laboratory Aspect of Trial

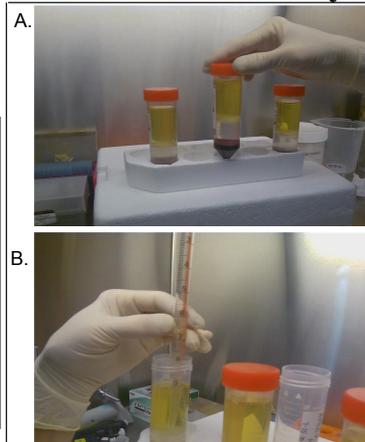


FIGURE 1. A and B shows the separation of the patients blood into plasma, serum and leukocytes. B shows the process of removing the leukocytes for processing.

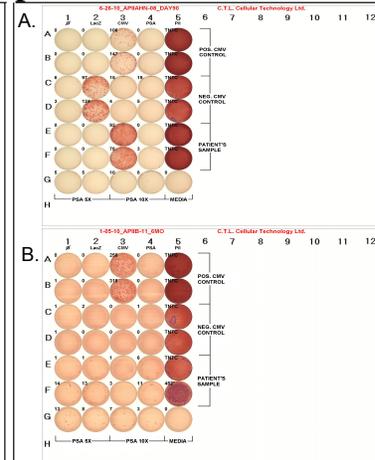


FIGURE 2. A and B shows T cell analysis by ELISPOT for two patients at 90 days and 6 months follow ups respectively.

Treatment and Shadowing

The following surgeries were observed:

- Cystoprostatectomy with male urinary diversion (neobladder)
- Robotic assisted laparoscopic prostatectomy (Removal of prostate using a robot)
- Brachytherapy (Planting radiation seed in the prostate)
- Penile implant (for patients with erectile dysfunction after cystoprostatectomy or other surgeries involving the reproductive organ or urinary tract)
- Transurethral resection of the prostate (TURP) (scraping of the prostate to allow patients flow of urine)
- Cystoscopy (Scope bladder)
- Retrograde Pilogram (dye in Kidney)
- Vantas implant (Yearly implant of hormonal treatment for prostate cancer patients)
- BCG treatment for patients with bladder cancer. This is a superficial bladder cancer treatment. This treatment will not work for anything that is muscle invasive or is already outside the bladder.

Conclusion

- The performance of a clinical trial is multileveled involving the participation of basic scientists, clinicians, nurse practitioner, physician's assistant, clinical trial coordinators, investigational pharmacists, research assistants and the staff in the clinical research unit.
- Exchange of information about the status of enrolled patients, discussions of new patients and presentation of results of both the clinical and laboratory data obtained during the trial.
- The anatomy and physiology of the male's reproductive organ and urinary tract was better understood based on the different surgeries observed and the treatments given for different diagnosis such as prostate, kidney or bladder cancer and erectile dysfunction

Future Directions

- The enrollment and treatment of patients into both protocols will continue until the targeting number of patients is reached.
- Results of the immunological testing and clinical evaluations will be discussed and the changes that may enhance the therapeutic efficacy of the vaccine will be considered.
- New trials of the vaccine may include combinations that would enhance the immunologic and clinical endpoints. These may include the vaccine in combination with low dose chemotherapy, agents that would induce cell death (apoptosis), or through nanoparticle delivery.

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