

RESEARCH STUDY

**Disease**

Kidney Disease

Protocol Title

Velcade® Therapy For Severe IgA Nephropathy

Principal Investigator

Choli Hartono, MD

Contact Information

Choli Hartono, MD
(212) 746-9708

Miriam Chung, MD
(212) 746-7647

Aline Baday, Study Coordinator
(212) 746-9911

Study Status

Recruiting

Brief Summary of Protocol

This study is aimed at subjects who have severe IgA nephropathy, a very common form of kidney disease where abnormal immunoglobulins type A (IgA), a natural antibody produced in plasma cells to protect infections, accumulate in the kidney and cause irritation and inflammation. There is currently no effective treatment for this condition.

The purpose of this study is to determine what effects Velcade® can have in patients with IgA nephropathy. Velcade® is approved by the US FDA for the treatment of multiple myeloma, a cancer of plasma cells, but it can also act on non-cancerous normal plasma cells that produce abnormal antibody proteins. Previous studies done elsewhere have suggested that Velcade® may interfere with pathways leading to inflammation in the kidney.

Patients who are found eligible for the study after the screening visit will be seen at the New York Hospital/Weill Cornell Medical Center CTSC (Clinical and Translational Science Center) outpatient unit and at The Rogosin Institute Outpatient Clinic to receive the medication through a vein in 1 to 2 cycles of 4 doses. Each dose is given at 72 hours interval. If there is no response to the medication (measured by blood and urine analysis) at the first cycle, a second will be initiated approximately a month later. Follow-up visits, involving physical examinations, blood and urine collections, will take place monthly thereafter for a total participation in the study of one year. Throughout the study, the principal investigator and study doctors will monitor all the medications taken, regardless of their indication.

Millennium Pharmaceuticals, Inc. is the company manufacturing Velcade®. Millennium will be providing the medication throughout the study, The Rogosin Institute is the sponsor of the study.

Treatment Overview (Potential Benefits)

There may or may not be direct benefits to participants. The presence of protein in the urine might not get better, or may even get worse during the study. However new information may be collected that may benefit patients with IgA nephropathy in the future.

IRB Information

Weill Cornell Medical Center IRB
407 E 61st Street – 1st Floor
New York, NY 10065
Protocol # 1001010854