Vaccine Therapy for Patients with Metastatic Melanoma

A Randomized Phase II Clinical Trial: Activation of pDCs at the Tumor and Vaccine Site with a Toll Like Receptor (TLR) Agonist

Objective:

- To compare the ability of vaccine in combination with Toll Like Receptor (TLR) stimulation at the site of vaccine to vaccine alone in the ability to enhance the generation of circulating tumor reactive T-cells

Eligibility Criteria:

- HLA-A*0201 positive (to enable immunization with the HLA class I restricted gp100(g209-2M) peptide
- Patients > 18 years old with histologically documented metastatic melanoma with measurable disease, stage IIIC (in transit lesions) or stage IV M1A with disease that includes lesions accessible for biopsies
- ECOG performance status of 0-1
- At least 4 biopsiable cutaneous lesions

Benefits for Patients:

- May induce an immune response leading to disease regression in patients

Procedures:

- A Randomized trial has two parts:
  - In Part 1 of eight-week time period, patients either receive gp100 (g209-2M) +MAGE3 peptite vaccine plus a topical TLR 7/8 agonist (ARM A), or the gp100 (g209-2M) +MAGE3 vaccine alone (ARM B)
  - In Part 2 of four-month time period, the cutaneous lesions are randomized to receive R848
- Patients come to MDACC weekly for 8 weeks, then every month for 4 months
- Subcutaneous and intradermal injections +/- gel will be given weekly for first 8 weeks
- Patients apply gel to lesions twice weekly at home for the following 4 months
- Physical exams and blood draw are done at nine clinic visits
- Apheresis and punch biopsies are done at three clinic visits

Protocol # 2008-0416

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Schedule an appointment or make referral online at https:// my.mdanderson.org or call (713) 563-9716.
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For information on related articles or references for this study, visit http://physicianrelations.org or http://www.clinicaltrials.gov/ct2/show/NCT00714103

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