New Adelaide Melanoma Vaccine Trial

The Effect of Timed Therapy in Patients with Advanced Melanoma

Australia has the highest rate of melanoma in the world and this rate is increasing – with approximately one patient being diagnosed every hour, and 4 patients dying of melanoma per day. Advanced melanoma survival remains dismally poor with the best currently approved therapies delivering a 5-year survival of about 1-2%, and with rate of complete regression of all melanoma of only <5%.

For more than12 years, a safe, non-toxic melanoma vaccine treatment for advanced melanoma, has been tested in a study of over 50 patients, and has seen results showing a complete response (CR) rate (where all cancer disappears) of nearly 17%, importantly, with little to no side effects. The 5-year survival rate in that study was just over 15%.

Part of the success of this treatment appears to be due to the 'timing' of therapy in coordination with each patient's own immune systems fluctuations. The immune system of each cancer patient appears to be repeatedly switching 'on' and 'off' causing an oscillation or cycle, which has been observed in patients with other cancer types also. Precisely when the dose of vaccine (or other therapy) is given in relation to the patient's own cycle appears to influence whether a successful response in the patient occurs or not.

This study aims to test whether the timing of delivery of therapy to patients with advanced melanoma (Stage III/IV), and who are not candidates for surgery, affects patient outcomes.

This project is looking for men and women who:

- Have been diagnosed with Stage IIIB/IIIC or Stage IV Melanoma
- Live in the greater Adelaide area and are able to attend Royal Adelaide Hospital regularly
- Are between 18 and 80 years of age and meet other strict entry criteria

Participants will undergo multiple series of daily blood tests to isolate and identify a "cycle" in their immune system.

Half of the participants will receive a vaccine which is delivered ‘timed’ according to this cycle. The other half will receive the vaccine at regular pre-determined intervals, in a similar way to the previous study. If disease progression occurs then chemotherapy is added to the vaccine treatment, also in a ‘timed' vs 'untimed' manner. Patients must fulfil strict criteria and the study is 'randomised' so that participants cannot choose which arm of the study they are in.

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