

**Title of Research**

Study to investigate the predictive value of serum LDH for immunotherapy related toxicity in patients with advanced melanoma

**Lead Researcher**

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**Data Sharing Agreement Effective Date**

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**Summary of Research**

The outcome of patients with advanced melanoma has greatly improved since the introduction of immunotherapy. Treatment with ipilimumab or nivolumab, both types of immunotherapy with different mechanisms of action, has proven to be an effective treatment modality in patients with advanced melanoma. However, recently updated results of the Checkmate-067 trial, comparing treatment with either ipilimumab, nivolumab or a combination of these two therapies, has shown a superior outcome in patients treated with the combination ipilimumab and nivolumab. However, patients with high levels of serum lactate dehydrogenase (LDH) clearly had less chance for response to therapy. Also, treatment related toxicity was seen more frequently in patients treated with the combination therapy compared to the single agent treatment. Many biological markers have been studied to predict response to immunotherapy, but less is known about predictive biomarkers to predict toxicity. This raises the question if serum LDH levels can also be of predictive value for the occurrence of treatment related toxicity.

Primary objective: To determine the predictive value of serum LDH for the occurrence of grade 3/4 treatment related toxicity. Primary endpoint: Occurrence of grade 3/4 treatment related toxicity.

**Study Design**

The researchers will use a retrospective database post-hoc analysis.

**Study Population**

Patients included in the Checkmate-067 trial treated with single-agent ipilimumab, single-agent nivolumab or a combination of nivolumab and ipilimumab

**Funding Source of Research**

Bristol Myers Squibb

**Requested Study**

Checkmate-067

**Statistical Analysis Plan** (added after publication)

**Publication Citation** (added after publication)