Karius Test for Detecting Bloodstream Infections in Immunocompromised Patients Prior to Onset of Symptoms

THE PREDSEQ TRIAL

Prediction of Bloodstream Infection Prior to Onset of Symptoms by Plasma Metagenomic Sequencing in Pediatric Patients with Relapsed or Refractory Malignancy (PREDSEQ)

Kathryn Goggin, MD1, Yuki Inaba, BS1, Veronica Gonzalez-Pena, PhD1, Kim J. Allison, BSN1, Ka Lok Chan, MS1, Desiree Hollemon, MSN, MPH2, Asim Ahmed, MD2, David Hong, MD2, Gabriela Maron, MD1, Randall Hayden, MD1, John Choi, MD, PhD1, Jeffrey Rubnitz, MD PhD1, Charles Gawad, MD, PhD1 and Joshua Wolf, MBBS FRACP1

(1) St. Jude Children’s Research Hospital, Memphis, TN, (2) Karius Inc., Redwood City, CA

The Karius Test identified bloodstream infections prior to the onset of clinical symptoms in high-risk pediatric cancer patients.

PATIENT POPULATION

This prospective cohort study enrolled 31 high-risk pediatric patients with leukemia or relapsed leukemia. Bloodstream infections (BSI) were defined according to National Healthcare Safety Network criteria.

RESULTS

A total of 11 BSI episodes occurred in 9 participants during the study period.

Predictive sensitivity of the Karius Test in the 2 days before onset of infection (n = 9) was 78% (95% CI 40 – 99.7%), and diagnostic sensitivity on the day of infection (n = 11) was 82% (48 – 98%).

Specificity of the Karius Test for development of fever or infection within 7 days (n = 10) was 80% (95% CI 44 – 98%).

The Karius Test was positive up to 6 days prior to onset of BSI. In samples collected before or during documented infections, the Karius Test also identified multiple additional uncultured bacteria and fungi.