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BLOOD-BASED BIOMARKERS FOR IL-23 INHIBITOR RESPONSE IN IBD

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Value Proposition: *Diagnostic method that uses the patient's PBMCs acquired before or immediately after the onset of IL-23 therapy to determine the presence of signatures indicative of long-term IL-23 response.*

Technology Description

Researchers at Washington University in St. Louis have developed a blood-based assay that measures the intracellular levels of certain cytokine biomarkers in IL-23 responsive immune cells. Inflammatory Bowel Diseases (IBD) such as Crohn's Disease (CD) and Ulcerative Colitis (UC) can be treated using a variety of therapeutics, including IL-23 blocking antibodies. However, the response rates of moderate to severe IBD patients to any one of these therapeutics seldom exceed 50%. It is also not possible to know from the outset which patients will fail to respond to certain therapeutics, and several weeks of ongoing treatment is needed before clinical outcomes are apparent. This can risk unnecessary delays in putting patients on alternative therapeutics that might work better before their disease progresses further. Unlike competing assays that measure secreted cytokine levels, this approach potentially offers more accurate determination of anti-IL23 response before or soon after treatment starts.

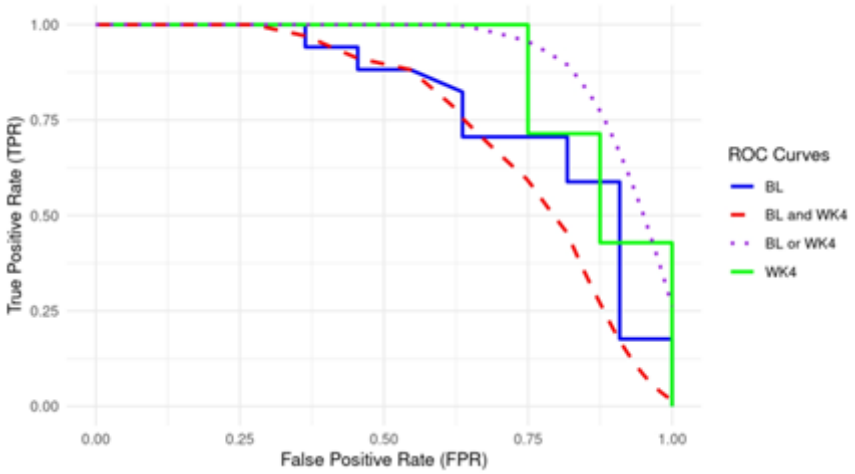

Figure – An example of ROC curve looking at intracellular Tnf-alpha levels in IL-23 responsive iNKT cells. Patients were enrolled at Washington University; pre-treatment and 4-week post treatment samples were obtained. AUC is between 0.81 and 0.92.

Stage of Research

Locked on several biomarkers with expected AUC > 0.92. Additional validation and optimization are being carried out.

Applications

- Screen IL-23 therapy-naïve IBD patients who might or might not respond to anti-IL-23.
- Inform clinical decision making.
- Help recruit more suitable patient pool for IBD clinical trials.

Key Advantages

- There are no effective assays to determine IL-23 response for IBD patients. Serum cytokine measurements have been unreliable..

Patents

Provisional patent application filed.

Related Web Links: Deepak Parakkal, MBBS MS and Stewart Cao, MD PhD