A Novel Flow Cytometry Tool for Fibrosis Scoring Through Hepatic Stellate Cell Differentiation (Hadasit)

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Rifaat Safadi, Hadassah Ein Kerem, Department of Medicine, Gastroentrology

Need:

Nonalcoholic steatohepatitis (NASH) is a leading cause of morbidity and mortality with no effective therapy. However, there are numerous NASH drugs in clinical development, with a projected market during the 2020s of >$10B. The prevalence of NASH is ~7% worldwide and growing based on increasing rates of obesity and the metabolic syndrome, and the prevalence of NASH fibrosis is >1% (>4M in US).

Hepatic stellate cells (HSCs) are the major cell type involved in fibrosis and the anti-fibrotic activity of NK-cells is decreased in fibrosis, thus failing to prevent fibrosis associated with the progression of NASH. This unique feature can make NK-HSCs interaction a useful tool for the assessment of the fibrotic stage of a patient.

Currently liver biopsy is the gold standard for diagnosis of NASH, and is often avoided especially when only 1/50000 of the whole liver tissue is sampled during a liver biopsy, for which sampling error is of concern. This poses a major need for a non-invasive and accurate assay for diagnosis of the fibrotic state of a patient. Such an assay can be useful for companies developing therapeutics in order to monitor the outcome of their drug candidate as well as for diagnostics companies.

Findings:

NK cells isolated from heathy donors did not activate HSCs while NK cells from both F1 and F4 fibrosis grade patients exposed to HSCs, showed elevated activation markers of HSCs and differentiated the cells to four-subpopulations using the flow cytometry analysis. The findings were recently published and can be viewed in the following link
https://www.ncbi.nlm.nih.gov/pubmed/29517852

Indications/applications:

A diagnostic and prognostic tool for companies performing clinical trials in therapeutics for NASH to identify the fibrotic state of a patient, as well as a tool for physicians that can be sold as a kit by diagnostics companies.

Competitive Advantage

Studying liver microenvironment through the *in vitro* interplay between cells and evaluating phenotypic changes is of a great prognostic value and could be a non-invasive and competitive tool for diagnosing NASH with no need for liver biopsy.

Contact for more information:

Tal Almog ✉, 054-3187538

Hadasit Medical Research Services & Development Ltd

Mother & Child Pavilion, Hadassah Ein Kerem, Jerusalem , 91120 Israel
Phone: +972-2-6778757, Fax: +972-2-6437712, E-mail: skimhi@hadassah.org.il