# Baseline Patient Characteristics and Non-Invasive Image Analysis in a Phase 2 Therapeutic Trial of GR-MD-02 in NASH Patients with Stage 3 Fibrosis

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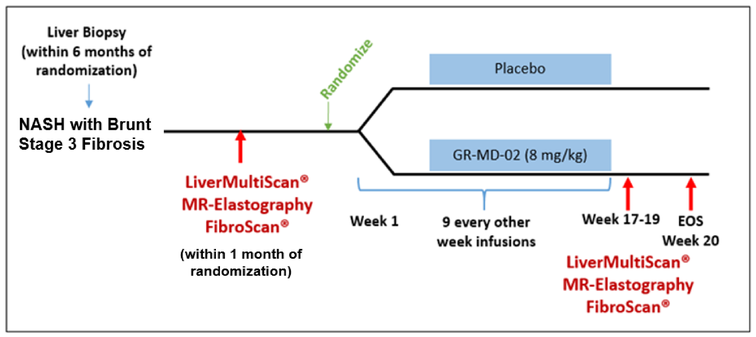
**Introduction:**

- Non-invasive approaches to the assessment of non-alcoholic steatohepatitis (NASH) with various degrees of fibrosis in the context of clinical trials is an important goal for drug development.
- Three leading candidates for non-invasive monitoring include multi-parametric magnetic resonance imaging (LiverMultiScan, LMS), liver stiffness measurement using vibration controlled transient elastography (FibroScan, FS), and liver stiffness measurement using magnetic resonance elastography (MRE).

**Objective:**

- To examine the baseline patient characteristics and the relationship between LMS, FS, and MRE in an ongoing single site trial of the antifibrotic GR-MD-02 in NASH patients with stage three fibrosis.
- (https://clinicaltrials.gov/ct2/show/NCT02421094?term=GR-MD-02&rank=6 )

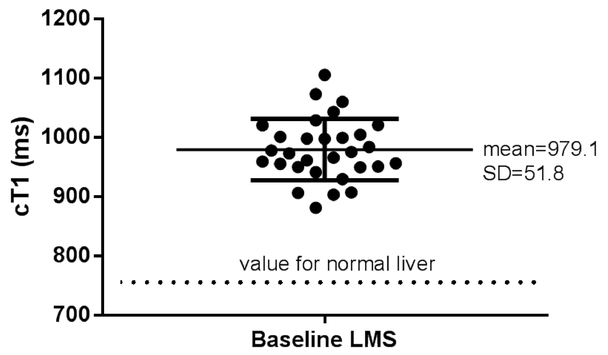
A Randomized, Controlled, Double-blind, Parallel Group, Single Center Phase 2 Clinical Trial to Evaluate Multiple Non-Invasive Liver Fibrosis Imaging Methods in the Assessment of the Efficacy of GR-MD-02 for the Treatment of Liver Fibrosis in Patients with NASH with Advanced Fibrosis

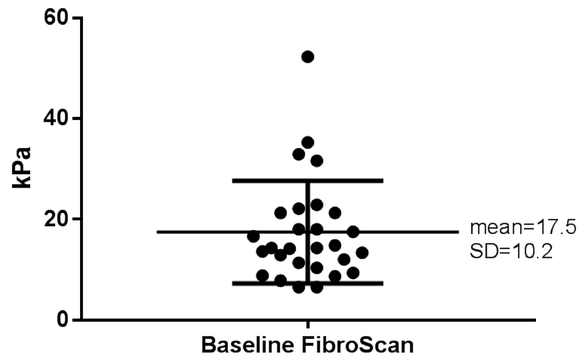


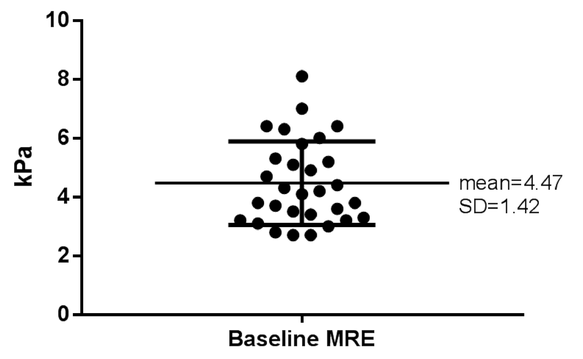

- **LiverMultiScan (LMS):** Multi-parametric magnetic resonance imaging for evaluation of liver disease. Corrected T1 parameter (measured in milliseconds) evaluates interstitial liver space. Perspectum Diagnostics, Oxford UK, developed the methodology and evaluated all scans in this study.
- **FibroScan:** Vibration-controlled transient elastography to evaluate liver stiffness. Echosens developed method and evaluated all digital files of exams in this study.
- **Magnetic resonance elastography (MRE):** Evaluations of liver stiffness were conducted on the same Siemens instrument and analysis done and reviewed by single radiologist.

## Subject Baseline Characteristics

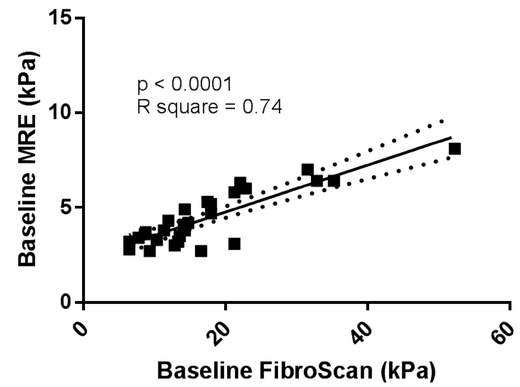
| Number | Sex (M/F) | Hispanic | Diabetes | Hypertension | Age mean (SD) | Height (in) mean (SD) | Weight (lbs) mean (SD) | BMI mean (SD) | ALT (U/L) mean (SD) |
|---|---|---|---|---|---|---|---|---|---|
| 30 | 17/13 | 12 | 25 | 21 | 58 (6.3) | 66 (8.8) | 214 (50) | 34.3 (5.7) | 55 (33) |

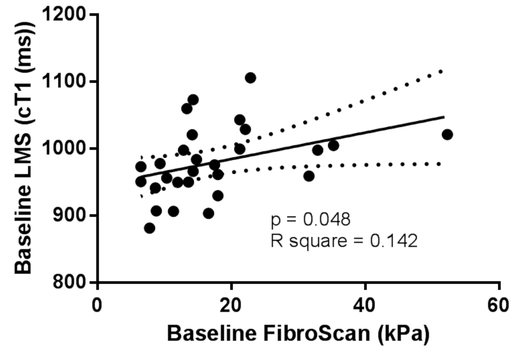


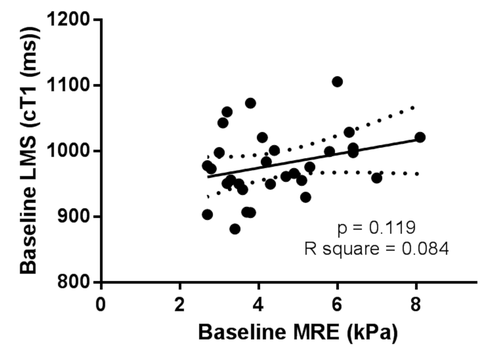




## Correlation of Baseline non-invasive tests




**Conclusions**:

- Liver stiffness measured by FS and MRE, both of which have been shown to relate with the degree of liver fibrosis, are well correlated in this cohort of NASH patients with biopsy proven stage 3 fibrosis.
- LMS, which is a composite of steatosis, inflammation and fibrosis is not well correlated to either measure of liver stiffness, possibly because it evaluates a combination of fibrosis and necro-inflammation.