Despite NAFLD/NASH being a prevalent co-morbidity in obesity and type 2 diabetes, the clinical development of NAFLD/NASH therapeutics is currently hindered by significant challenges in clinical trial enrollment. Traditional study screening is commonly associated with screen failure rates of greater than 90%. Given the cost- and time-intensive implications of subjects failing to meet MRI- or biopsy-based inclusion criteria, there is a clear need for optimized screening strategies in NAFLD/NASH clinical trials.

**AIM**

Our goal was to assess the potential utility of an integrated screening approach aimed at pre-identifying individuals who have a high probability of being eligible for NAFLD/NASH clinical studies.

**MATERIALS & METHODS**

Our integrated screening approach consists of:

1) A NAFLD scoring system based on the combined use and analysis of 2 screening algorithms published in the literature.

2) A lipidomic testing panel for both NAFLD and NASH.

3) Application of a Non-Invasive Integrated Screening Algorithm to Improve Enrollment in NAFLD/NASH Clinical Trials.

- **Algorithm 1**
  -fatty liver
  -NASH index: BMI + rel conc. of 20 triglycerides
  -NAFLD index: BMI + rel conc. of 11 triglycerides

- **Algorithm 2**
  -NASH index: BMI + rel conc. of 20 triglycerides
  -NAFLD index: BMI + rel conc. of 11 triglycerides

- Both algorithms were tested on 35 subjects undergoing MRI-PDFF with liver fat >5%.

Conclusions:

- These preliminary results point to the potential utility of optimized, non-invasive screening algorithms for NAFLD/NASH studies.

- Pre-screening strategies to identify individuals who are most likely to have significant steatosis or steatohepatitis on MRI or biopsy may be a scalable, efficient means of reducing screen failure rates in NAFLD/NASH clinical trials.

**REFERENCES**


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