

## Background

- ❖ Screen failure (SF) reasons in non-cirrhosis NASH trials have been described; however, limited data exists on the reason for screen failure reasons in NASH cirrhosis trials.
- ❖ The aim of this study was to understand the reasons for screen failure in 5 NASH cirrhosis trials and to describe the patient's characteristics of both screens failed subjects and those who randomized.

## Methods

- ❖ Patients who presented for screening visits for three phase 2 NASH cirrhosis trials at one research site were analyzed.
- ❖ Reasons for screen failure were divided into 4 major categories: 1. Biopsy, 2. Laboratory tests, 3. Imaging/Procedure 4. Other.
- ❖ Baseline characteristics including demographics, clinical history, lab values, findings from imaging tests and biopsy
- ❖ 2-sided t-test performed, p value < 0.05 was considered statistically significant.

Table 1-Patient Characteristics

	Mean	Mean	Mean	
	Total population	Randomized arm	Screen fail arm	T-test
Age	58.31	60.95	56.88	
BMI	37.38	39.88	37.05	
HbA1c	6.42	6.43	6.46	
%Diabetes	52.90%	48.50%	51.40%	
Platelets	177.23	159.26	187.3	0.13
bilirubin	0.795	0.83	0.76	0.52
INR	1.13	1.15	1.12	0.24
kPa	23.31	24.03	22.24	0.79
Agile 4	0.44	0.518	0.42	0.23
CAP Score	302.35	310.33	297.57	0.59
Fib 4	3.12	2.95	3.41	0.53

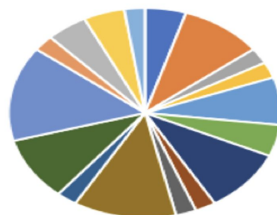
## Results

- ❖ 68 patients included - 23 randomized (33.8%) and 45 screen failed (66.17%).
- ❖ The mean age was 57.98 years with 45% Male
- ❖ Mean BMI in the whole population was 38.38 Kg/m<sup>2</sup>. 51.47 % of the patients have type 2 diabetes.
- ❖ Reasons for screen failure : 4 (8.8 %) on biopsy, 12 (26.6%) on labs, 11 (24.4%) on imaging, 15 (33.3%) for other reasons.
- ❖ Top 3 causes included in the other category were patients out of the screening window, using prohibited medicine, dropping out of the trial, or presence of esophageal varices
- ❖ No significant difference between the screen failure group and the randomized group in terms of platelet count, INR, bilirubin, FIB4 score and AGILE4 score (p > 0.05 for all)

## Conclusion

NASH cirrhosis trials have similar screen failure rates compared to non-cirrhosis trials; however, the reasons for screen failure are different. In NASH cirrhosis trials, fewer patients screen failed because of not meeting histologic criteria on liver biopsy which has been the major reason for screen failure in non-cirrhosis trials. Baseline laboratory and imaging tests were not different between patients who screen failed and those who randomized.

Screen Failure Minor Causes



- High MELD
- positive for Varices
- Lost to follow up
- Low platelet
- Elevated Bilirubin
- NAS
- could not finish procedure
- Out of window
- Uncontrolled HTN
- Fibrosis
- Bariatric surgery
- Subject dropped
- EKG abnormality
- Elevated Hba1c
- MRI-PDFF
- prohibited meds
- Blood alcohol +