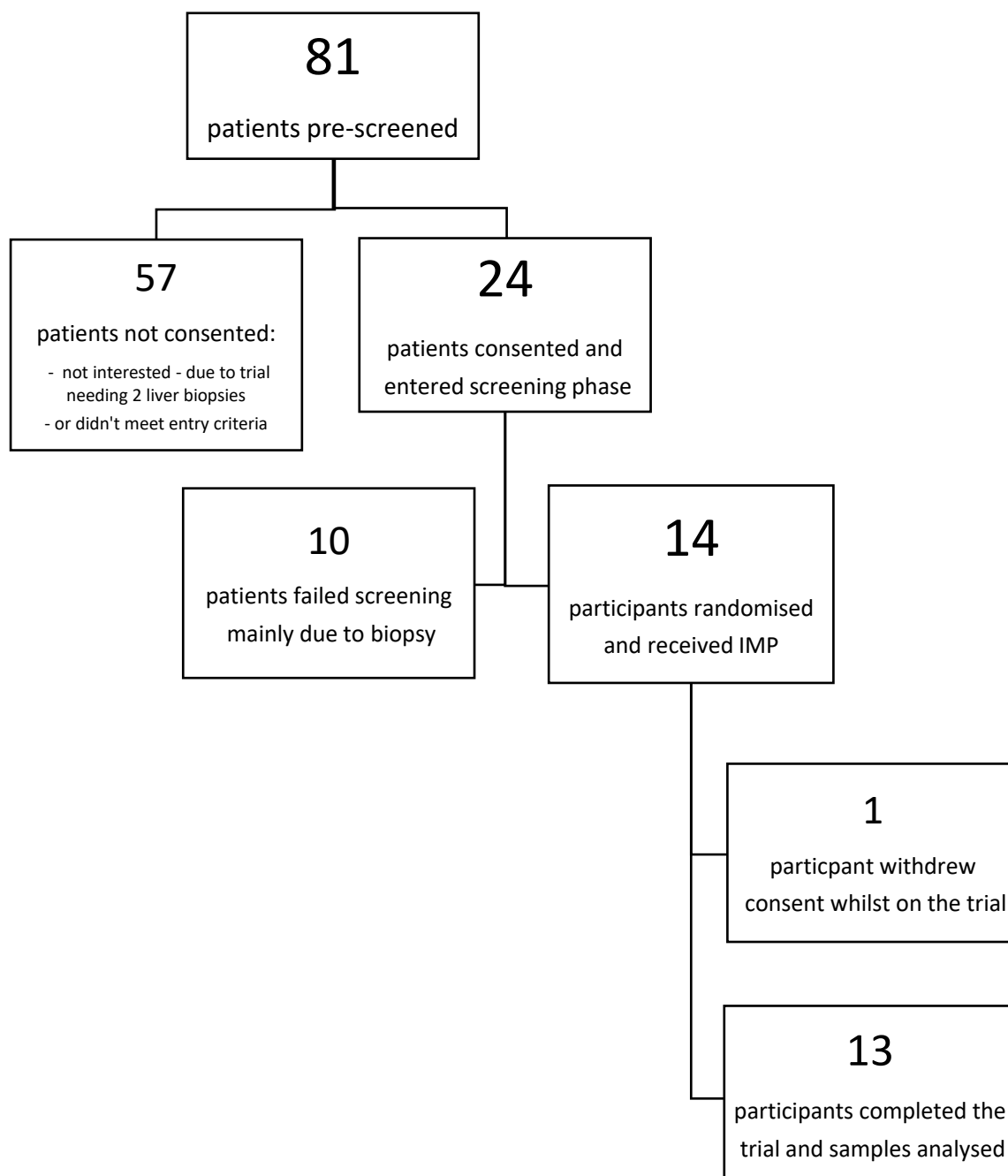


# Investigating the impact of Maraviroc on liver inflammation in patients with HIV and fatty liver disease - Basic Results Summary

## Participant Flow:



**Baseline characteristics of the 13 patients with treatment completion and paired liver biopsies:**

<b>Age, years, median (range)</b>	50.5 (43-59)
<b>Sex (%)</b>	Male 13 (100%)
<b>Ethnicity (%)</b>	Caucasian 12 (92%) Asian 1 (8%)
<b>Clinical Characteristics</b>	
Bodyweight (kg)	97.96 ± 16.51
BMI (kg/m <sup>2</sup> )	30.66 ± 4.075
Waist circumference (cm)	107.38 ± 11.62
Glucose concentration (mmol/L)	6.68 ± 2.024
Insulin (IU/ml)	28.81 ± 2.93
HOMA-IR	8.96 ± 9.91
TG (mmol/L)	2.055 ± 1.30
TC (mmol/L)	4.35 ± 1.038
HDL (mmol/L)	1.075 ± 0.33
LDL (mmol/L)	2.68 ± 0.83
ALT (U/L)	77.15 ± 40.87
AST (U/L)	50.33 ± 25.48
GGT (U/L)	88.46 ± 43.50
Neutrophil count (x10 <sup>9</sup> /L)	3.72 ± 1.53
Lymphocyte count (x10 <sup>9</sup> /L)	2.35 ± 0.74
Liver biopsy size (mm) median (range))	25 (17-49)
NAS, median (range)	4 (4-6)
<b>Fibrosis</b>	<b>Week 0</b>
0	0 (0%)
1a	0 (0%)
1b	1 (8%)
1c	1 (8%)
2	4 (32%)
3	7 (54%)

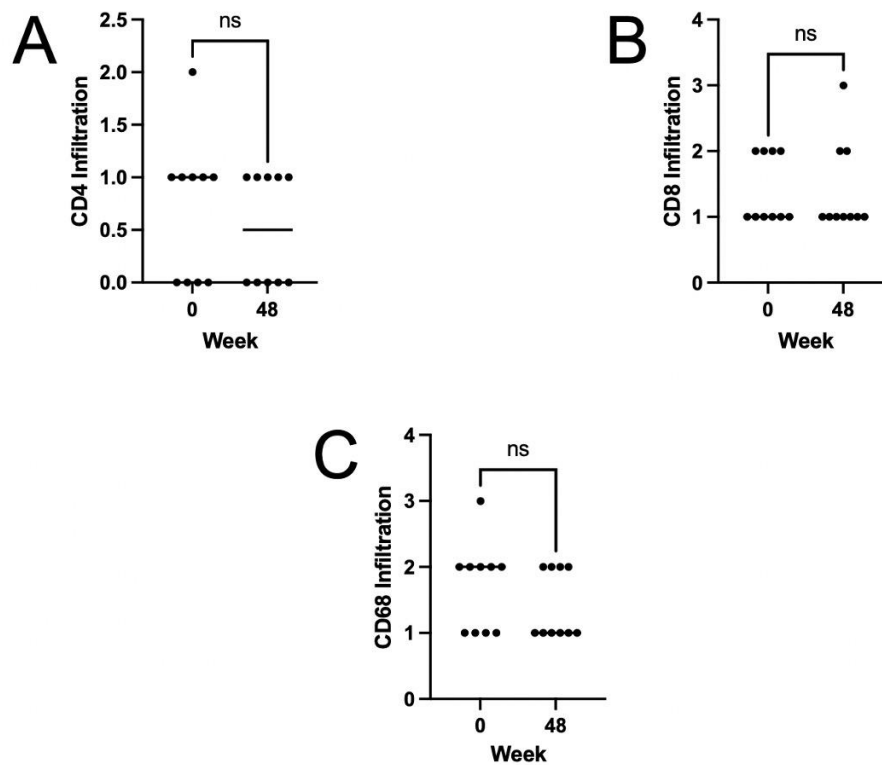
BMI: Body Mass Index; HOMA-IR: Homeostasis model of insulin resistance index; TG: Triglycerides; TC: Total cholesterol; HDL: High-density lipoprotein; LDL: Low-density lipoprotein; ALT: alanine aminotransferase; AST: Aspartate aminotransferase; GGT: Gamma-glutamyl transferase; NAS: NAFLD Activity Score  
Data is in mean ± standard deviation or median (range)

### Primary Outcome:

**Histological outcome of liver lesions at week 48 compared to baseline:**

	<b>Regressed:</b>	<b>Stable:</b>	<b>Progressed:</b>
<b>Steatosis</b>	3(23)	7 (58)	1 (8)
<b>Inflammation</b>	3 (25)	8 (75)	0
<b>Hepatocytic ballooning</b>	2 (15)	7 (54)	2 (15)
<b>Fibrosis</b>	4 (31)	4 (31)	3 (23)

Scatter plot showing semi-quantitative histological scoring for CD4 (A), CD8 (B), and CD68 (C), ns = non-significant:



### Conclusion:

The MASH study could not demonstrate a significant beneficial effect on liver lesions, inflammation or metabolism of 48 weeks add-on maraviroc in HIV-infected individuals with NASH.

**Adverse Events:**

Site	Patient Number	SUSAR/SAE	Event #	Start Date	End Date	Status	Description of Event	Causal Relationship	Expected (Y/N)
Chelsea & West	2-005	SAE	1	16/09/2019	17/09/2019	resolved	Hospitalisation for monitoring of high blood pressure.	Not related to IMP	N
Chelsea & West	2-005	SAE	2	11/10/2019	13/10/2019	resolved	Hospitalisation post liver biopsy due to pain. Chest XRay showed evidence of free sub phrenic gas under right diaphragm	Not related to IMP	N

Please note that the Protocol did allow for hospitalisations for elective treatment of a pre-existing condition. These did not need reporting as SAEs.