#3255 Abstract

Thermal ablation plus toripalimab in patients with advanced hepatocellular carcinoma: Phase I results from a multicenter, open-label, controlled phase I/II trial (IR11330)

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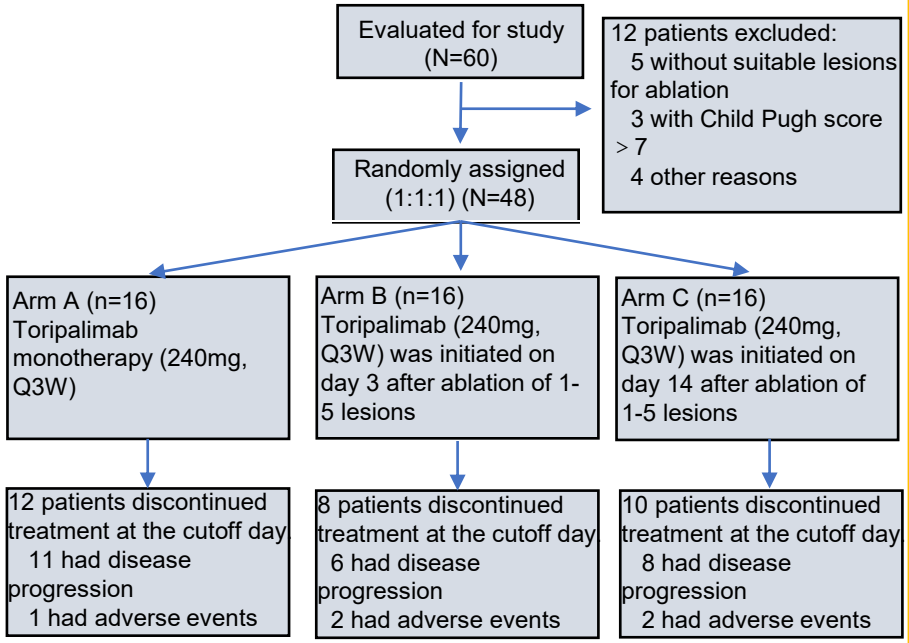
1 Background

Thermal ablation has been showed to induce immunogenic cell death and enhance the effect of PD-1 blockade in preclinical study. The trial was designed to evaluated the safety and efficacy of ablation plus toripalimab in advanced HCC. Phase I results on time scheduling, safety and preliminary antitumor activity are reported.(NCT02974738)

2 Methods

Figure 1. Flowchart



3 Results

Table 1. Baseline of characteristics

Characteristics	All (n=48)	Arm A (n=16)	Arm B (n=16)	Arm C (n=16)	*P* value
Age (year)	54 (21-74)	53 (21-74)	57 (42-74)	51 (32-74)	0.336
Gender					0.859
Male	42	15	14	13	
Performance status					0.933
0	21	6	7	8	
1	27	10	9	8	
Etiology					0.859
Hepatitis B virus	42	13	14	15	
Hepatitis C virus	2	1	0	1	
No. of tumor					0.977
≤ 6	8	2	3	3	
7-10	21	8	7	6	
≥ 11	19	6	6	7	
MVI	13	5	3	5	0.775
Extrahepatic sites	29	10	11	8	0.661
BCLC Stage					1.000
B	7	2	3	2	
C	41	14	13	14	
Previous treatment					NA
Surgery	22	6	8	8	
TACE	28	10	8	6	
Sorafenib	32	12	9	11	
Lenvatinib	19	5	9	5	
Regorafenib	8	3	1	4	
Child-Pugh score					0.977
5	12	3	5	4	
6	25	9	8	8	
7	11	4	3	4	
Serum AFP (ng/mL)					0.979
< 200	18	6	7	5	
200-400	10	3	3	4	
> 400	20	7	6	7	

Table 2. Objective response rate n (%)

	Arm A	Arm B*	Arm C*	*P* value 1	*P* value 2	*P* value 3
ORR	3 (18.8)	6 (37.5)	5 (31.3)	0.433	0.685	1.000
DCR	12 (75.0%)	12 (75%)	11 (68.8)	1.000	1.000	1.000
CR	0	2 (12.5)	0			
PR	3 (18.8)	4 (25.0)	5 (31.3)			
SD	9 (61.6)	6 (37.5))	6 (37.5))			

* Evaluation of lesions outside of ablation area.
P value 1: Arm A vs. Arm B; P value 2: Arm A vs. Arm C; P value 3: Arm B vs. Arm C;

4 Conclusions

- Toripalimab monotherapy showed definite antitumor activity in previously treated HCC.
- Sequential subtotal thermal ablation and toripalimab led to a substantial increase of ORR, especially timing of toripalimab sooner after ablation.
- There were no unexpected toxicities resulting from both timing schedules of combination.
- Starting of toripalimab on day 3 after ablation was recommended for phase II evaluation.