

Hematological Toxicity (Japan)

Level	#Pts	WBC				Neutro				Hb				PLT				
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
1	3	1	1	1	0	0	1	1*	0	1	2	0	0	0	0	0	0	0
2	6	0	0	6	0	0	2	4*	0	1	3	0	0	0	0	0	0	0

* Usage of G-CSF

DLT: Level 1: 0/3, Level 2: 0/6

Non-hematological Toxicity (Japan)

Level	#Pts	U-GI				L-GI				GU				Skin				#cycle				
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	2	3	4	5	
1	3	3	0	0	0	1	1	0	0	1	0	0	0	3	0	0	0	0	2	0	1	
2	6	2	3	1*	0	1	2	0	0	0	0	0	5	1	0	0	1*	2	2	1		

* Fatigue: Grade 3

DLT: Level 1: 0/3, Level 2: 1/6

Summary of the Results

- 1. Acute toxicities of concurrent chemoradiotherapy using two dose levels of cisplatin (level 1: 30mg/m², level 2: 40mg/m²) were assessed.**
- 2. In the level 1, 0/3 patients developed the DLT. In the level 2, 1/6 patients developed the DLTs. From these results, the level 2 dose was determined the RD.**
- 3. In the level 2, the grade 3 neutropenia occurred in 4/6 patients, who needed the G-CSF for their myelosuppression.**
- 4. In the level 2, the grade 2-3 upper GI symptoms (nausea, vomiting, loss of appetite) occurred in 4/6 patients, who needed frequent administration of the ant-emetics.**