

The Strategy of Prednisone Reduction

For

TACTIC-SS - A Pilot Study in Severe Patients with Takayasu Arteritis.

Clinical Trial No.: NCT04300686

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Date: 2020-11-10

1. All the enrolled patients in TACTIC-SS were prescribed the strategy prednisone and methotrexate, as well as the biological agents adalimumab or tocilizumab according to the randomized group.
2. The dose of methotrexate is 15mg per week. The adalimumab is 40mg.q2weeks.IH, while the tocilizumab is 8mg/Kg.qm.IH.
3. The dose of prednisone was adjusted according to the following schedule.
4. The disease remission was defined as the disease status turning to inactivity.

Background glucocorticoid treatment (Routine Protocol)

		Prior prednisone less than 40mg.qd (active status)	Prior prednisone more than 40mg.qd	Prior prednisone less than 40mg.qd (inactive) or complicated with infection	Notes
months	weeks	Dose	Dose	Dose	
0	0	40	40	30	
1	2	35	35	30	
1	4	30	30	25	
2	6	25	25	25	
2	8	20	20	25	
3	12	15	15	20	
4	16	10	10	15	
5	20	10	10	10	
6	24	10	10	10	
Biological agents switched if the disease remission was not achieved, and the prednisone would return to 40mg.					
7	28	10	10	10	
8	32	5	5	5	
9	36	5	5	5	
10	40	5	5	5	
11	44	5	5	5	
12	48	2.5	2.5	2.5	
Extended follow-up with prednisone free. If relapse occurred during follow-up, patients exited the investigation.					
13	52	2.5	2.5	2.5	
14	56	2.5	2.5	2.5	
15	60	0	0	0	
16	64	0	0	0	
17	68	0	0	0	
18	72				

Notes:

Prednisone adjustment for special conditions.

1. If infection occurs (antibiotics needed), the prednisone would sustain the current dose and would not decrease till next month. Correspondingly, the biological agents would also suspend for a month as well.
2. After the initial 6 months' treatment, the biological agent strategy would be switched to the opposite if the disease remission could not be achieved, and the prednisone would return to 40mg as well.
3. The target dose of prednisone is 0 mg at the 48-week. Subsequently, patients would be followed up with prednisone free for another 6 months. If relapse occurred during this period, patients would exit the study immediately.