The efficacy and safety of *Tripterygium wilfordii* Hook F in the treatment of active rheumatoid arthritis

With the support by the National Natural Science Foundation of China (Grant Nos. 81325019, 81172859 and 81273312), Dr. Zhang Xuan's group at the Department of Rheumatology and Clinical immunology, Peking Union Medical College Hospital, reported the result of a randomized, controlled clinical trial (TRIFRA) which compared the efficacy and safety of *Tripterygium wilfordii* Hook F (TwHF) with methotrexate (MTX) in the treatment of active rheumatoid arthritis (RA). The study was published in *Annals of the Rheumatic Diseases* (**2014**, 0: 1—9).

In this TRIFRA trial, 207 patients with active RA were recruited and randomly allocated (1:1:1) to treatment with MTX 12.5 mg once a week, or TwHF 20 mg three times a day, or the two in combination. Ten patients in each monotherapy group were switched to MTX+TwHF group because of lack of efficacy at week 12 and 174 patients completed 24 weeks of the trial. In an intention-to treat (ITT) analysis, the proportion of patients reaching the ACR50 response criteria at week 24 was 46.4%, 55.1% and 76.8%, respectively, in the MTX, TwHF and MTX+TwHF groups. A significant difference was found between the treatment efficacy of TwHF and MTX monotherapy by the non-inferiority test ($P=0.014$), when the comparison of the combination treatment and MTX monotherapy showed a significant difference by the χ^2 test ($P<0.001$). Similar statistically significant patterns were found for ACR20, ACR70, clinical Disease Activity Index good responses, EULAR good response, remission rate and low disease activity rate. These results were supported by that of per-protocol (PP) analysis. In the safety evaluation, there was no statistically significant difference of the frequency of adverse events among the three groups ($P>0.05$).

In conclusion, this TRIFRA study showed that TwHF monotherapy was not inferior to, and combination therapy of MTX+TwHF was better than, MTX monotherapy in controlling disease activity in patients with active RA. It also indicated that the combination of TwHF and MTX is a safe and efficacious treatment for patients with active RA.

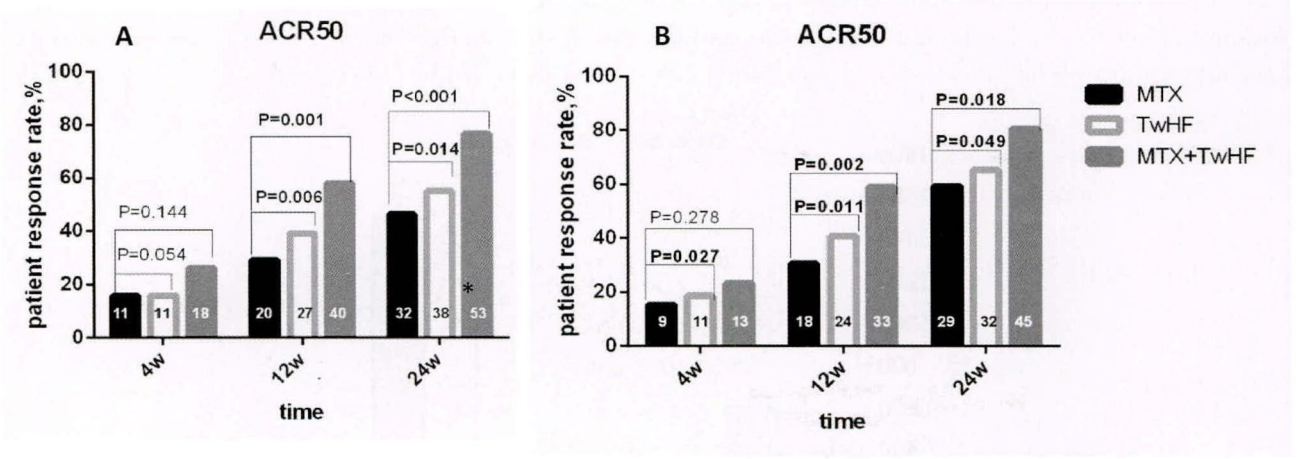

Figure Primary efficacy measures over time in ITT analysis (A) and PP analysis (B). * The number within each bar represents the patients who reached the response criteria in each group. The percentage of response was calculated with the denominator of total enrolled patients (69 for each group) in ITT analysis and patients who finished the originally allocated treatment schedule (49, 49, and 56 for the methotrexate (MTX) in PP analysis).