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AB0196 SURVIVAL ANALYSIS OF TIME TO FIRST ADVERSE DRUG REACTION AND DRUG SURVIVAL IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH ADALIMUMAB AND ETANERCEPT

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Background: Treatment of rheumatoid arthritis (RA) with biologic disease-modifying antirheumatic drugs (bDMARDs) has been common practice in the last two decades. However, differences in patients experiencing adverse drug reactions (ADRs) between individual bDMARDs, such as adalimumab (ADA) and etanercept (ETN), during first time treatment has not been studied yet in real-world settings.
Objectives: To compare proportions of RA patients experiencing ADRs as well as survival to first ADR and drug survival during treatment with ADA and ETN.
Methods: Retrospective single centre cohort study including adult patients with RA, treated with either ADA or ETN between 1 January 2003 and 30 April 2020. The proportions of patients experiencing an ADR were compared by assessing the percentage of patients, treated with either ADA or ETN, experiencing at least one ADR during their first time treatment. Survival to first ADR and drug survival were assessed by calculating time between start of treatment and first ADR and start of treatment and discontinuation of treatment respectively. Stop and restart of treatment within 90 days was considered as continuous use. Differences in proportions were statistically tested using Fisher's Exact Test. Differences in drug survival between ADA and ETN were tested by Kaplan-Meier analysis and Log Rank tests.
Results: A total of 422 patients were included in this study (ADA 259, ETN 163). For 93 patients (21.2%) an ADR was registered during first time treatment. The proportion of patients experiencing at least one ADR during their first time treatment was 22.7% for ADA and 20.2% for ETN (p=0.628). Survival time to first ADR did not differ significantly between ADA and ETN (median survival ADA 10.34 years (95% CI [7.62-13.06], median survival ETN not reached, p=0.109, figure 1A). Median drug survival was 1.75 years for ADA (95 CI [1.38-2.11]) and 2.68 years for ETN (95% CI [1.73-3.64]). Drug survival differed significantly (p<0.001, figure 1B).

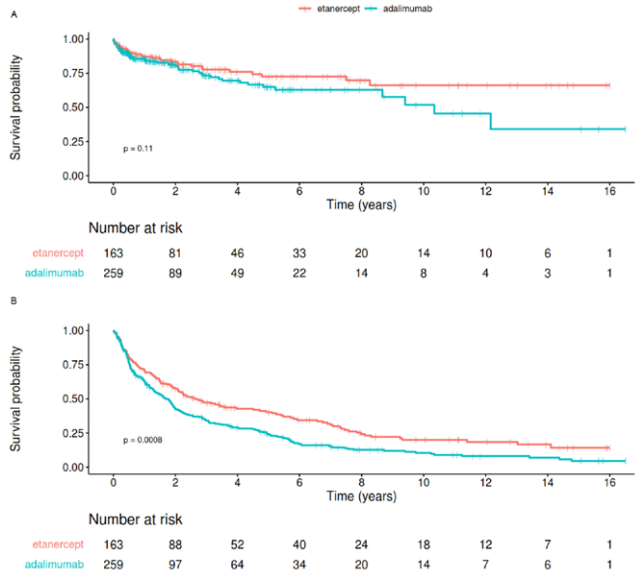

Figure 1. Kaplan-Meier survival curves for adalimumab and etanercept with (a) survival to first ADR and (b) drug survival.

Conclusion: Neither the proportion of patients experiencing ADRs nor survival to first ADR during first time treatment with ADA and ETN differed significantly. Drug survival of first time drug treatment of ADA was significantly lower compared to drug survival of first time drug treatment of ETN.
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AB0197 EFFICACY AND SAFETY OF HLX01 COMBINED WITH METHOTREXATE IN CHINESE PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS WHO HAD INADEQUATE RESPONSES TO METHOTREXATE: RESULTS OF A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 3 STUDY

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Background: Rituximab is an effective therapy for rheumatoid arthritis (RA) patients with inadequate responses to methotrexate (MTX)[1, 2]. However, it has not been registered or approved in China for the treatment of RA by far. HLX01, an approved rituximab biosimilar (demonstrated in Chinese patients with diffuse large B-cell lymphoma)[3], is thus evaluated in this study for the benefits of Chinese RA patients.
Objectives: This study aimed to evaluate the efficacy and safety of HLX01 plus MTX versus placebo plus MTX in Chinese patients with active RA who had inadequate responses to MTX.
Methods: This was a randomised, double-blind, placebo-controlled phase 3 study conducted in China (NCT03522415). Eligible patients were randomised 2:1 to receive intravenous infusion of 2×1000 mg HLX01 or placebo on day 1 and day 15. Patients with inadequate responses at week 16 and 20 were allowed to receive rescue treatments. Patients were retreated with or switched to receive (if initially assigned to placebo) 2×1000 mg rituximab at the first day of week 24 and 26. The primary endpoint of this study was the American College of Rheumatology criteria (ACR) 20 response at week 24. Secondary efficacy endpoints were evaluated at week 12, 24, 36 and 48. The safety, pharmacokinetics, pharmacodynamics and immunogenicity of HLX01 were observed and analyzed throughout the study.
Results: Between May 28, 2018 and Sep 11, 2020, a total of 275 patients (ITT set) were randomised and 263 patients without major protocol deviations were included in per-protocol set (PPS). At week 24, HLX01 showed statistically superior efficacy (p <0.001) to placebo (ACR20: 60.7% vs 35.9% in ITT set, 60.3% vs 37.1% in PPS). Secondary efficacy endpoints were also significantly improved in HLX01 group compared with placebo (Table 1). The overall incidence of serious treatment emergent adverse events (TEAEs), adverse drug reactions (ADRs), and TEAEs leading to drug discontinuation were similar among treatment groups, with the most common TEAE been upper respiratory tract infection before (18.1% vs 18.5%) or after (13.0% vs 12.3%) week 24. Serum concentrations, immunogenicity and pharmacodynamics were similar between HLX01 and placebo groups.