Risk of Adverse Drug Events Due to Baricitinib 2 mg Versus Baricitinib 4 mg Once Daily for the Treatment of Rheumatoid Arthritis

SCIENCE

Abstracts

Key Take-Away:

This is the first study which compared baricitinib 2 mg versus 4 mg in patients with rheumatic arthritis (RA). The total adverse events, discontinuation of the drug due to adverse events, malignancies, major adverse cardiac events, infections like herpes zoster, and serious infections were significantly higher between the two doses of Baricitinib at 24 weeks follow-up.

Introduction:

On 23 April 2018, the FDA-based Advisory Committee approved the use of baricitinib 2 mg for RA treatment and suggested the possibility of serious adverse events associated with baricitinib 4 mg. Therefore, the authors aimed to systematically distinguish between the risk of adverse drug events observed with baricitinib 2 mg against 4 mg for the treatment of RA patients.

Methods:

The electronic database, for example, the Cochrane Library, MEDLINE, EMBASE, were explored for relevant English publications until April 2018. The adverse drug events at 12 weeks and 24 weeks were regarded as the clinical endpoints. RevMan 5.3 software was used to analyze the data whereby risk ratios (RR) and 95% confidence intervals (CI).

Results:

Four trials consisting of 959 participants were included in this analysis. At 12 weeks, no significant difference was seen between 2 mg and 4 mg baricitinib concerning the serious adverse events (RR 1.33; 95% CI 0.63–2.78; $p = 0.46$), any adverse events after the initiation of therapy (RR 1.09; 95% CI 0.98–1.21; $p = 0.13$), discontinuation of drugs because of adverse events (RR 1.19; 95% CI 0.61–2.34; $p = 0.60$), major adverse cardiac events (RR 2.95; 95% CI 0.12–71.91; $p = 0.51$) and malignancies (RR 3.03; 95% CI 0.12–73.90; $p = 0.50$). Infections, for instance, herpes zoster infections and severe infections, were also similarly manifested. At 24 weeks, severe adverse events (RR 1.84; 95% CI 1.02–3.30; $p = 0.04$) were significantly increased with baricitinib 4 mg as compared to 2 mg dosage. Nevertheless, total adverse events after the start of therapy, discontinuation of the drug due to adverse events, malignancies, major adverse cardiac events, infections comprising herpes zoster, and serious infections were not significantly different between the two doses.

Conclusions:

No major dissimilarities found to be associated with adverse drug events between baricitinib 2 mg and 4 mg at 12 weeks' follow-up were observed. But, this analysis depicted the risk of serious adverse events to be significantly higher with baricitinib 4 mg as compared to baricitinib 2 mg at 24 weeks' follow-up. This hypothesis should be executed in more extensive trials with longer follow-up periods.

Source:	BioDrugs
Link:	https://link.springer.com/article/10.1007%2Fs40259-018-0304-3
Original title of article:	Risk of Adverse Drug Events Observed with Baricitinib 2 mg Versus Baricitinib 4 mg Once Daily for the Treatment of Rheumatoid Arthritis: A Systematic Review and Meta-Analysis of Randomized Controlled Trials
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Therapeutic, Baricitinib, Janus kinase (JAK) inhibitor, Rheumatoid arthritis, Systematic Review, Meta-Analysis, Randomized Controlled Trials, Malignancies, Cardiac events, Infections, Herpes zoster, RevMan 5.3 software