THE RATE OF POSITIVE CONVERSION IN THE QUANTIFERON-TB GOLD TEST OVER 2 YEARS AMONG PATIENTS TREATED WITH CT-P13 OR INNOVATOR INFliximAB IN THE EXTENSION STUDIES OF PLANETAS AND PLANETRA

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Background: Long-term treatment of anti-TNF agents in patients with immune mediated disease can increase the risk of active tuberculosis infection (ATBI) by reactivation of latent tuberculosis infection (LTBI) or de novo infection. CT-P13 is a biosimilar of innovator infliximab (INX), approved by the EMA in 2013 based on the studies PLANETAS and PLANETRA.

Objectives: To identify the risk of positive conversion in the QuantiFERON®-TB Gold in-tube (QTF) test over 2 years in ankylosing spondylitis (AS) and rheumatoid arthritis (RA) patients receiving CT-P13 or INX in the extension studies of PLANETAS and PLANETRA, in 17 countries with various TB incidences.

Methods: Of 476 enrolled subjects in extension studies of PLANETAS or PLANETRA, all patients had QTF test at baseline and at least one follow-up QTF result after study drug exposure for a 110-week period. Patients with positive QTF result at baseline received prophylaxis before study drug exposure. Patients received either CT-P13 or INX (5mg/kg in AS; 3mg/kg in RA) by usual schedule up to week 102. Countries were divided into four risk groups according to TB incidence, as listed in the 2013 WHO TB report: very low (0–19/100000 population), low (20–49), intermediate (50–124) and high (≥125). In prevalent countries, QTF was performed at weeks 14, 30, 54, 62 and 110. In countries with low risk, QTF was performed at weeks 62 and 110 (or the end of the study visit). To identify the positive conversion in QTF test, patients with negative result at baseline were included in this analysis.

Results: Among 458 patients with negative QTF at baseline, median dose is 15 (range 9 to 15) and all patients had at least one QTF result after 9th dose exposure. Positive conversion of QTF was observed in 16.6% (76/458) of patients (AS 18.5% [31/168]; RA 15.5% [45/290]). The results showed a tendency of higher positive conversion rate in the region where the TB incidence is high (very low 9.3%, low 11.4%, intermediate 21.7%, high 52.0%). Relative risk (RR) of positive conversion in intermediate and high vs. very low and low TB incidence countries was 2.37 (95% CI 1.57 to 3.59). Among 458 patients with negative QTF at baseline, median dose is 15 (range 9 to 15) and all patients had at least one QTF result after 9th dose exposure. Positive conversion of QTF was observed in 16.6% (76/458) of patients (AS 18.5% [31/168]; RA 15.5% [45/290]). The results showed a tendency of higher positive conversion rate in the region where the TB incidence is high (very low 9.3%, low 11.4%, intermediate 21.7%, high 52.0%). Relative risk (RR) of positive conversion in intermediate and high vs. very low and low TB incidence countries was 2.37 (95% CI 1.57 to 3.59). Non-white ethnicity had higher RR of positive conversion in very low and low TB incidence countries (RR 3.83, 95% CI 2.04 to 7.21), and intermediate and high TB incidence countries (RR 3.11, 95% CI 1.89 to 5.10) as well. In very low, low, intermediate and high incidence countries, positive conversion was observed in 9.3%, 8.5%, 19.6% and 48.0% of patients with negative QTF at baseline.

Conclusions: To reduce TB incidence in patients receiving anti-TNF agents, appropriate screening and serial QTF tests at least during the first two years of treatment are necessary to reduce and minimize the risk of TB in patients residing in intermediate and high TB endemic regions.


DOI: 10.1136/annrheumdis-2014-eular.3492