Post-marketing experience in the safety profile of Interferon beta- 1b biosimilar product in relapsing-remitting multiple sclerosis: 7 years' follow-up

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Abstract

Background:
Interferon (INF) beta 1b was the first disease-modifying drug (DMD) approved by the FDA for the treatment of relapsing-remitting multiple sclerosis (RRMS) in 1998. Regarding potentially long-term use of established DMDs in MS treatment, data evaluation of safety profile on a large group of patients for appropriate duration is recommended.

Objectives:
The goal of this study is an evaluation of long term safety outcomes of biosimilar product of INFβ-1b(Ziferon®; 300 mcg vial) produced by Zistdaru Danesh biopharmaceutical company in Iranian patients with RRMS over seven years.

Method:

A non-interventional cohort study was conducted on 5311 patients from Aug 2011 to March 2019. The patients had a confirmed and documented diagnosis of RRMS as defined by the Revised McDonald Criteria (2010), were ambulatory with a Kurtzke Expanded Disability Status Scale score of 0 to 5.5, and their treatment by Ziferon 300 mcg subcutaneously every other day was just started. Safety profile, including adverse drug reactions (ADRs), and its severity and related-laboratory tests were monitored over seven years.

Results:
The most common reported adverse drug reactions during period of the time were injection site reaction (69.38%), flu-like symptoms (21.99%), central nervous system (3.5%), musculoskeletal system (2.03%), and gastrointestinal (1.96%) which all were mild to moderate and rarely caused treatment discontinuation. Injection site reactions were the most common reason for drug discontinuation.

Conclusion:
The present post-marketing study confirms long term tolerability and safety outcomes of biosimilar product of INF beta 1 b (Ziferon®) in Iranian RRMS patients was acceptable and no new alarming signal was detected during the study period.