

Biosimilars 2016: Biosimilars in treatment of multiple sclerosis in Iran

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The estimated number of multiple sclerosis patients increased from 2.1 million in 2008 to 2.3 million in 2013. In Iran, the prevalence of multiple sclerosis increased from 45/100,000 in 2011 to 54.5/100,000 in 2013. In capital, multiple sclerosis prevalence had increased from 51.9/100,000 in 2008 to 74.28/100,000 in 2011. In fact, the incidence of multiple sclerosis significantly increased from 3.77 in 2007 to 5.68/100,000 in 2013, annually. Various reports show the significant increased economic burdens multiple sclerosis on patients, on their families, and on government. A biosimilar drug is a biologic medical product which is almost a matched copy of a reference "innovator" product that is synthesized by a different company. Biosimilars are a new class of drugs intended to offer comparable safety and efficacy to the original, off-patent biological. Indeed high expenses of many biological medicines have led to the development of biosimilars in Iran similar to other countries. Development of biosimilars is not feasible because of structural complexity, manufacturing process and the possible risk for immunogenicity. The main limitations with biosimilar are that, the two biosimilars have a different origin, the two biosimilars may have same therapeutic effect, may have different side-effects and hence require thorough testing. There are several biosimilars that are prescribed for multiple sclerosis patients in Iran. In 2005, CinnoVex™ as the first biosimilar IFN-beta-1a was produced in Iran and is still available in the market. About 2/3 of patients with multiple sclerosis in Iran are on biosimilars. Of note, the efficacy and safety of such products were assessed and established in different experimental and clinical controlled studies.

The potentially disabling disease of brain and spinal cord is said to be Multiple Sclerosis. The protective sheath that covers the nerve fibers will

be attacked by the immune system in the multiple sclerosis. The protective sheath causes the communication problems between brain and the rest of the body. Ultimately, the disease can cause permanent damage or damage to the nerves.

The signs and symptoms of multiple sclerosis can differ significantly from person to person and over the course of the disease, depending on the location of the affected nerve fibers. Symptoms often affect movement, such as weakness or numbness in one or more limbs, which usually occurs on one side of your body at a time, or your legs and trunk; sensations of electric shock that occur with certain movements of the neck, in particular when bending the neck forward (Lhermitte's sign); tremors, lack of coordination or unsteady gait.

Vision problems are also common, including: partial or complete loss of vision, usually in one eye at a time, often accompanied by pain during eye movements; prolonged double vision and blurred vision.

Symptoms of multiple sclerosis can also include: slurred speech; tired; dizziness; tingling or pain in certain parts of your body; problems with sexual, intestinal and bladder function. The signs and symptoms of multiple sclerosis vary widely and depend on the amount of nerve damage and the nerves affected.

Most people with multiple sclerosis take a course in relapsing-remitting disease. They experience periods of new symptoms or relapses that develop over the course of days or weeks and generally improve partially or completely. These relapses are followed by calm periods of remission of the disease which can last for months or even years. Small increases in body temperature can temporarily worsen the signs

and symptoms of multiple sclerosis, but they are not considered to be true relapses of the disease.

At least 50% of people with relapsing-relapsing multiple sclerosis eventually develop a steady progression of symptoms, with or without periods of remission, within 10 to 20 years of the onset of the disease. This is called secondary progressive multiple sclerosis. Worsening symptoms usually include mobility and gait problems. The rate of disease progression varies widely among people with secondary progressive multiple sclerosis. Some people with MS experience a gradual onset and steady progression of signs and symptoms without relapse, called progressive primary multiple sclerosis.

The cause of multiple sclerosis is unknown. In the case of multiple sclerosis, this dysfunction of the immune system destroys the fatty substance that covers and protects the nerve fibers of the brain and the spinal cord (myelin). Myelin can be compared to the insulating coating of electrical wires. Messages that travel along the nerve fiber can be blocked or slowed down when the protective myelin is damaged.

Some of the risk factors of developing multiple sclerosis are:

Age. Multiple sclerosis can occur at any age, but it usually starts around 20 and 40 years of age. However, the young and the older may be affected.

Sex. Women are two to three times more likely than men to have relapsing-relapsing multiple sclerosis. Certain infections.

Various viruses have been linked to multiple sclerosis, including Epstein-Barr, the virus that causes infectious mononucleosis.

Family story. If one of your parents or siblings has multiple sclerosis, you are at a higher risk of developing the disease.

Vitamin D. Low vitamin D levels and low exposure to the sun are associated with an increased risk of multiple sclerosis.

Certain autoimmune diseases. You have a slightly higher risk of developing multiple sclerosis if you have other autoimmune disorders such as thyroid disease, pernicious anemia, psoriasis, type 1 diabetes or inflammatory bowel disease.

Weather. Multiple sclerosis is much more common in temperate countries, including Canada, the northern United States, New Zealand, southeast Australia and Europe.

Race. Whites, especially those of North European descent, are most at risk of developing multiple sclerosis. People of Asian, African or Native American descent present the lowest risk.

Muscle stiffness, paralysis, problems with sexual function, mental changes like mood swings, depression etc. are some of the complications that develop in people with multiple sclerosis.

Most people with multiple sclerosis do not die from it, although some studies suggest that it reduces life expectancy by six or seven years. What can kill people with multiple sclerosis are the complications of the disease, including lung infections (pneumonia) and sepsis, a potentially fatal reaction to the infection.

