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Neuroprotective effect of silymarin on diabetic peripheral neuropathy in streptozotocin-induced diabetic rat model

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Background: Diabetic neuropathy is the most common complication of diabetes mellitus. Oxidative stress is considered the key mechanism in the diabetic peripheral neuropathy (DPN) therefore; Silymarin may have a neuroprotective effect against the development of DPN via its anti-oxidant activity.

Objectives: In this study, we investigate the possible effects of silymarin on DPN using STZ diabetic rat animal model.

Methods: Forty-five male albino rats will be used along the study. Diabetes will be induced by a single Intra-peritoneal injection of Streptozotocin (STZ). All rats with BGL (blood glucose level) ≥ 250 mg/dl will be randomly assigned into 2 groups; Silymarin group receiving 100 mg/kg/day of Silymarin by oral gavage for 2 months and Diabetic group receiving equal amount of saline for same duration. Behavioral tests will be done; including open field assessment of vertical and horizontal motor activities and tail immersion test for thermal hyperalgesia. At the end of the experiment, morphological, histopathological, biochemical and immunohistochemical changes of sciatic nerve will be examined.

Results: This is an ongoing research and the experiment is still underway. We anticipate finding a possible neuroprotective effect of Silymarin in delaying the development of diabetic peripheral neuropathy in diabetic rats.

Conclusions: The current work will add more evidence to the use of Silymarin as one of non-conventional medications of DPN. Silymarin can be used simultaneously as an adjuvant therapy to delay the onset of DPN in diabetic patients.

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How to market generics and bio-similars in Saudi Arabia

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Kingdom of Saudi Arabia (KSA) is considered one of the most matured markets of the six Gulf Cooperation Council (GCC) member states with generic drug penetration, and as healthcare expenditure as a percentage of GDP is increasing (expected to be 5.16% by 2015), there is an opportunity for the generic market to grow. There are currently 24 manufacturers in KSA, with 11 more under registration. Some local trends discussed were the strategic partnerships local manufacturers have with multinationals, the increased capacity and expansion at local manufacturing as well as increased Contract Manufacturing (CMO) being done for foreign companies. While local KSA manufacturers do enjoy a majority generic drug market share, foreign drug companies are also entering KSA. There is a focus on increased share of distribution, increase in strategic alliances with local manufacturers, as well as an increase in the number of clinical trials being conducted in KSA for branded drugs.

In general, the Saudi FDA (SFDA) regulations governing are very similar to FDA regulations, which guarantee the need for worldwide harmonization. Exceptions adopted to meet the specific needs for Saudi Arabia and GCC countries are of course considered. "How to market generics and bio-similar in Saudi Arabia" gives comprehensive aspects such as legal framework, provisions affecting generic/bio-similar development and commercialization, reference medicinal product/generic listing or catalogue, requirements for registration & registration/evaluation process, format and content of the application, labelling/product monographs, fees, pharmacovigilance/post marketing surveillance, pricing and reimbursement, prescription and supply, and advertisement/promotion.

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