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Comparative Efficacy and Tolerability of 5-Loxin® and Aflapin® Against Osteoarthritis of the Knee: A Double Blind, Randomized, Placebo Controlled Clinical Study

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Abstarc :

Aflapin® is a novel synergistic composition derived from *Boswellia serrata* gum resin (Indian Patent Application No. 2229/CHE/2008). Aflapin is significantly better as an anti-inflammatory agent compared to the *Boswellia* extracts presently available in the market. A 90-day, double-blind, randomized, placebo-controlled study was conducted to evaluate the comparative efficacy and tolerability of 5-Loxin® and Aflapin® in the treatment of osteoarthritis (OA) of the knee (Clinical trial registration number: ISRCTN80793440). Sixty OA subjects were included in the study. The subjects received either 100 mg (n=20) of 5-Loxin® or 100 mg (n=20) of Aflapin® or a placebo (n=20) daily for 90 days. Each patient was evaluated for pain and physical functions by using the standard tools (visual analog scale, Lequesne's Functional Index, and Western Ontario and McMaster Universities Osteoarthritis Index) at the baseline (day 0), and at days 7, 30, 60 and 90. A battery of biochemical parameters in serum, urine and hematological parameters in citrated whole blood were performed to assess the safety of 5-Loxin® and Aflapin® in OA subjects. Fifty seven subjects completed the study. At the end of the study, both 5-Loxin® and Aflapin conferred clinically and statistically significant improvements in pain scores and physical function scores in OA subjects. Interestingly, significant improvements in pain score and functional ability were recorded as early as 7 days after initiation of the study in the treatment group supplemented with 100 mg Aflapin. Corroborating the improvements in pain scores in treatment groups, our *in vitro* studies provide evidences that Aflapin® is capable of inhibiting cartilage degrading enzyme MMP-3 and has the potential to regulate the inflammatory response by inhibiting ICAM-1. Aflapin® and 5-Loxin® reduce pain and improve physical functions significantly in OA subjects. Aflapin exhibited better efficacy compared to 5-Loxin®. In comparison with placebo, the safety parameters were almost unchanged in the treatment groups. Hence both 5-Loxin® and Aflapin® are safe for human consumption.

Key Word :
Aflapin®, 5-Loxin®, Boswellia serrata, anti-inflammation, osteoarthritis and clinical study

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