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P140 — 2015

Safety and Efficacy of Liposome Intraarticular Injection in Moderate Knee Osteoarthritis: A RCT

Nonoperative treatment (Knee)
Presented on Tuesday, March 24, 2015 7:00 AM

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INTRODUCTION: Osteoarthritis of the knee is a debilitating disease, and efficient nonoperative treatment is still to be discovered. Reducing pain and improving patients' activity is the main current goal. However, most treatments, including intraarticular injections of hyaluronic acid (HA), do not provide satisfactory results. The articular cartilage in adults consists of layers. The amorphous lipid layer is composed of proteoglycans, glycoproteins, hyaluronic acid, liposomes and lamellar phases, and is bound to phospholipid zone cartilage. MM-II is a novel intraarticular bio-lubricant that provides long-term effect by using liposomes as mechanical lubricants. This product is a dispersion that consists of liposomes suspended in water. The liposomes are constructed by two different types of synthetic sourced phosphatidylcholine, DMPC and DPPC. Those phosphatidylcholines form multilamellar vesicles in the water. Multilamellar liposomes have an onion structures. Typically, several unilamellar vesicles will form one inside the other in diminishing size, creating a multilamellar structure of concentric phospholipid spheres separated by layers of water. In vitro, MM-II provides mechanical lubrication, ease cartilage surface gliding, prevent further cartilage wear & friction coefficient, and eliminate additional joint damage and deterioration. This prospective randomized double blinded study was designed to compare safety and efficacy of intraarticular MM-II as compared to hyaluronic acid injections.

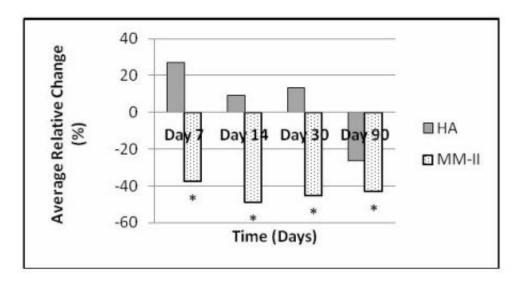
METHODS: Forty patients with unilateral knee osteoarthritis were recruited for the study. Only patients with moderate radiographic (Lawrence Kelgreen stage 2-3) and clinical (pain VAS score between 40 and 80) osteoarthritis were included. Forty patients were randomized into two groups, receiving single dose injection of either MM-II or hyaluronic acid. Both patients and investigators were blinded to the type of medication injected. Patients were followed for three months. Pain VAS score in rest and during activity and WOMAC score were measured before the injection and 7, 14, 30, and 90 days afterwards. Knee range of motion and overall patient satisfaction were measured as well. All injection-related complications were recorded. All patients received acetaminophen as a rescue medication and recorded its consumption. All patients completed the study.

RESULTS: The average age and BMI was similar in the two groups. No significant adverse reactions were noted throughout the study. Forty percent reduction in pain was observed in the MMII group after 14 days, compared to later improvement in the HA group (figure 1). Significant improvement in performing the daily activities was seen after seven days only in the MM-II group. Stiffness was improved in both groups.

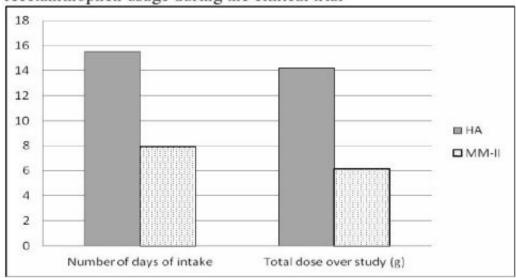
DISCUSSION: MM-II was found to be safe and tolerant in intraarticular injections for knee osteoarthritis. In this first clinical trial it showed faster and better improvement in pain and activity than a single-dose hyaluronic acid injection.

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## Patient's Relative Change in Pain in Target Knee over Time



Acetaminophen usage during the clinical trial



**Disclosure:** L. Kandel: 3B, 5 - Moebius Y. Dolev: 3B, 5 - Moebius R. Shimonov: 3B, 5 - Moebius G. Rivkin: 3B, 5 - Moebius M. Liebergall: 3B, 5 - Moebius Y. Mattan: 3B, 5 - Moebius Y. Barenholz: 3B, 5 - Moebius X. Chevalier: 3B, 5 - Moebius

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