# SAFETY AND EFFICACY OF A SINGLE INJECTION OF MANNITOL-MODIFIED CROSSLINKED HYALURONIC ACID (HAPPYMINI®) IN TRAPEZIOMETACARPAL OSTEOARTHRITIS: A MULTICENTER OPEN-LABEL TRIAL

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## OBJECTIVES

To assess the safety and to obtain preliminary data on the efficacy on pain relief of a single intra-articular injection of a new mannitol-modified hyaluronic acid (HANOX-M-XL) viscosupplement, in patients suffering from trapezio-metacarpal (TMC) osteoarthritis (OA).

## Treatment

**HANOX-M-XL** (Happymini ®, Laboratoire LABRHA, Lyon, France) is a novel viscosupplement, that combines:

- ►**high concentration** (16 g/L) of **cross-linked sodium hyaluronate** of non-animal origin
- ►**high concentration** (35 g/L) **of mannitol,** a polyol known for its antioxidant properties by scavenging radical oxygen species (ROS)

## METHODS 1

Patients with symptomatic TMC OA were included in a 3 month prospective multicentre open-label trial. Investigators were rheumatologists or orthopedic surgeons, specialized in hand OA.

To be included in the study patients must have symptomatic TMC OA, not adequately relieved by analgesics/ NSAIDs therapy and/or by the use of a thumb orthotics.

Patients with inflammatory arthritis, trapezo-scaphoidal OA and those who previously received intra-articular injections with corticosteroids into the target thumb were excluded.

Before treatment all patients must have had plain radiographs with the Kapandji incidences, for the Dell grade (0-4) assessment.

## METHODS 2

**Primary endpoints** were the variation between injection (D0) and D90 of the thumb pain on 11 point-Likert scale (0-10) and the patient's self-assessment of efficacy (0-3).

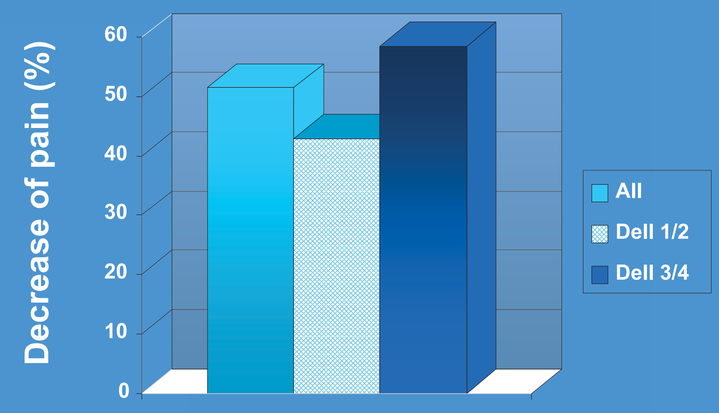
**Treatment** consisted in a single injection of 0.6 to 1 ml of HANOX-M-XL in the TMC joint under fluoroscopic guidance.

**Statistical tests** were carried out on ITT population . The statistical analysis was performed using Statview© software version 5.0 (SAS institute Inc).

*The study received the French health authorities approval and was conducted in accordance with the Ethical standards of the Declaration of Helsinki. EUDRACT N° 2015-AO1874-45*

## RESULTS

64 patients ( 54 F), aged (SD) 62.3 (10.1), were recruited. Thumb OA was bilateral in 68.7%.
Dell grade was 1 in 11 cases, 2 in 21 patients, 3 in 27 and 4 in 4 subjects (1 missing data).
At baseline the mean (SD) pain was 6.4 (1.7) without difference according Dell grade. At D90, 60.2% of patients considered the treatment as very effective or effective. **Between D0 and D90, pain decreased significantly from 6.4 to 3.1 (-51.5%) (p<0.0001)**. Pain relief was greater in patients with Dell 3/4 than in those with Dell 1/2 but the difference did not reach statistical significance ($\chi_2$ *P*=0.36).




12.6% of patients experienced local pain during or following HA administration, that resolved without sequel within 1 to 7 days.

## CONCLUSION

This pilot study suggests that a single course of HAPPYMINI® injection is effective in relieving pain in patients with TMC OA, without safety concern.

Interestingly patients with the more advanced stages of OA seemed to benefit more from the treatment than those with less advanced OA.

A placebo-controlled trial needs now to be performed to confirm these promising data.