CLINICAL TRIAL ON ELMORE OIL

TITLE:

Assessing the safety and efficacy of a herbal remedy, Elmore Oil, on pain and well-being in patients with osteoarthritis: A double-blind, placebo-controlled, randomised trial.

PRINCIPAL INVESTIGATOR:

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INTRODUCTION:

The treatment of osteoarthritis, a disease that eventually affects the majority of the older population, involves the alleviation of symptoms such as pain and stiffness, and the reduction of inflammation. A double-blind, placebo-controlled, crossover study is being performed to examine the effect of Elmore Oil, a herbal remedy (containing Olive Oil, Tea Tree Oil, Eucalyptus Oil and Vanilla), which has recently been reported to have analgesic and anti-inflammatory properties, on the symptoms of osteoarthritis.

METHODOLOGY:

This study was approved by the Veterans Memorial Medical Centre sub committee on human research.

Design: Cross-over experimental design

Sample Size: Since only one other pilot study (11 participants) had been performed on the efficacy of Elmore Oil on arthritic or other pain, a full study of 60 patients is being conducted. The sample size is not obtained through probability sampling.

PROTOCOL:

I. Sixty patients with osteoarthritis have been randomly allocated to treatment with either Elmore Oil daily or an identical placebo for 1 month, followed immediately by the alternative treatment. Patients have been classified “odd” or “even” dependant on the allocation of product.

II. The patients have been assessing changes in joint pain and stiffness after each treatment period on a 5-point categorical scale.

1. Nocturnal joint pain
2. Diffused pains around the knees after use and relieved by rest.
3. Joint stiffness that lasts less than one hour
4. Presence of coarse crepitations over the knees
5. The absence of inflammation

III. Patients are over 45 and under 90 years of age.

IV. Subjects have been solicited from patients attending The Rheumatology Clinic at the Veterans Memorial Medical Centre, Out Patient Department, in Quezon City, Philippines.

V. Selection of subjects with osteoarthritis is based on the criteria developed by the American College of Rheumatology.

VI. Subjects have been asked to grade their levels of pain and stiffness for a 1-week no-treatment baseline. Subjects were then asked to apply the herbal or placebo ointment to the involved joint(s) for 28 consecutive days and record their levels of pain and stiffness daily on visual analogue scales.

VII. Personal diary to record: Wellbeing, mood, sleep quality, and energy.

VIII. Blood tests have been performed at baseline and 28 days after treatment. This includes full blood examination, liver function tests, and kidney function tests, including a CRP and ESR and X-Ray (APL views) of the knee joint/s.

ASSESMENT OF EFFICACY:

The results in the two arms of the crossover are being compared.

Group A (placebo first and Elmore Oil after) are being compared within group to see if there is significantly more improvement from using Elmore Oil than from placebo for pain and for stiffness, including blood tests results.

Group B (Elmore Oil first and placebo later) are being examined if a positive effect of the same order as for Elmore Oil in group A, not only from the active drug, but also from placebo.

To see if an identical pattern is observed when general wellbeing etc., an evaluation from the diary records is being compared.

Patients, on the basis of joint pain, are divided into responders and non-responders. The first month of active treatment (group A) response rate will be compared to that of placebo (group B).

Side effects occurred, if any, in either group are being documented.

STASTICAL ANALYSIS:

Data has been described as means, standard deviations, frequency and percent distribution, To compare the degree of pain with the baseline within each treatment arm, Wilcoxon Matched Pairs Signed Rank Test will be used.

The same test will be used to compare the 2 treatment arms. Significance of change in dichotomous data will be carried out using the McNemar Test. A p-value of <0.050 will be considered significant.

CONCLUSIONS:

The trial commenced in December 2008 and concluded at the end of June 2009. Results for the Elmore Oil participants are discussed below:

<u>Assessment of pain by treatment and observation periods:</u>

Results showed no significant differences in pain levels at base line between the 2 groups. (expected)

Within the 2 groups, up to and including week 4, there were significant changes from baseline to week 2 and again through to week 4 in the Elmore Oil group.

Pain diaries and x-ray analysis from participants support the outcome so far that Elmore Oil provides significant relief from discomfort of osteoarthritis, while improved movement and reduced inflammation are also evident. Exact data conclusions are as follows (assessment over 4 week period):

Pain (assessed through VAS score)	-	average reduction of 33.33%
Number of days of severe joint stiffness	-	average reduction of 38.88%
Number of days of poor quality sleep due to pain & discomfort	-	average reduction of 73%

(See attached statistical data graphs attached for *pain levels* and the number of *no sleep* days for participants)

Safety:

No significant adverse reactions were reported by patients. Some minor itching and redness was reported around inflammation, but these were spasmodic and were determined to be insignificant.

No significant changes were noted in Haemoglobin, Hematocrit, WBC, SGOT or SGPT levels.

It would appear that the use of Elmore Oil does not cause any adverse side effects.

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