

Protocol Registration Receipt

04/22/2009

The Effects of Elmore Oil, on Patients With Osteoarthritis: A Double-Blind,
Placebo-Controlled, Randomised Trial.

This study is ongoing, but not recruiting participants.

Sponsored by:	Elmore Oil Company Pty Ltd
Information provided by:	Elmore Oil Company Pty Ltd
ClinicalTrials.gov Identifier:	

► Purpose

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 will be performed to examine the effect of topical application of Elmore Oil, a herbal remedy (containing Eucalyptus oil, Tea tree oil, Olive oil and Vanilla), which has recently been reported to have anti-inflammatory properties, on the symptoms of osteoarthritis.

Condition
Degenerative Arthritis Inflammation

Study Type: Observational

Study Design: Cohort, Prospective

Official Title: The Effects of a Herbal Remedy, Elmore Oil, on Pain and Well-Being in Patients With Osteoarthritis: A Double-Blind, Placebo-Controlled, Randomised Trial.

Further study details as provided by Elmore Oil Company Pty Ltd:

Primary Outcome Measure:

- Decrease in joint swelling, pain and stiffness after each treatment period [Time Frame: Every day for 28 days] [Designated as safety issue: No]

Secondary Outcome Measures:

- Detect changes in Full Blood Examination parameters, liver function tests, and kidney function tests, including a CRP and ESR. [Time Frame: 28 days] [Designated as safety issue: Yes]

Estimated Enrollment: 80

Study Start Date: November 2008

Estimated Study Completion Date: May 2009

Estimated Primary Completion Date: April 2009

Groups/Cohorts	Interventions
A Patients receive Elmore Oil.	
B Patients receive Placebo oil (olive oil base).	

 Eligibility

Population from which the cohorts will be selected are from hospital primary care arthritis clinic.

Sampling Method: Non-Probability Sample

Ages Eligible for Study: 45 Years to 90 Years

Genders Eligible for Study: Both

Inclusion Criteria:

- Diagnosed osteoarthritis based on the criteria developed by the American College of Rheumatology.

Exclusion Criteria:

- Using other forms of topical pain relief.

 Contacts and Locations

Locations

Philippines, Manila

Veterans Memorial Medical Centre

Quezon City, Manila, Philippines, 1100

Investigators

Study Director:

Letitia Lucero, MD

Veterans Memorial Medical
Centre

More Information

American College of Rheumatology
<http://www.rheumatology.org>

Responsible Party: Elmore Oil Company Pty Ltd (Mr Mark Linford)

Study ID Numbers: EO-01

Health Authority: Philippines: Bureau of Food and Drugs; Philippines: Department of Health