

Efficacy and safety of Sri Lankan Traditional Medicine Regimen for Knee Osteoarthritis

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INFORMATION SHEET

I am Dr. RHSK de Silva, attached to the Institute of Indigenous Medicine, University of Colombo. My current designation is Senior Lecturer. I would like to invite you to take part in the research study on “Working potential of Sri Lankan Traditional medicine treatment for Knee pain” supervised by Prof Saroj Jayasinghe at Faculty of Medicine and Dr.PK Perera at Institute of Indigenous Medicine, University of Colombo.

1. Purpose of the study

Objective of this study is to assess the effect of a Sri Lankan treatment regimen for the knee pain by administration of decoction with a pill, fomentation and applying a paste.

2. Voluntary participation

Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. Duration, procedures of the study and participant’s responsibilities

This study will be conducted over a period of three months. If you volunteer to participate in this study, we will ask you to do the following:

a) We will be supplied pre-prepared dried herbs seven packs to prepare decoction at home with 56 pills for rescue pain, paththu (paste) and pottani (fomentation herbal medicine bundle) for fomentation for external application for knee

or

(b) **Conventional medicines called** Tablet Paracetamol and for external application topical formulation of 2% Diclofenac Sodium gel and fomentation with warm water before applying it and participants on rescue medication with oral Ibuprofen tablet up to maximum dose of 800mg per day will be given for two weeks over two months.

If you are selected for the group of Decoction, paththu (paste) and pottani (herbal medicine bundle)

(a) 120-g of dried powder pack of decoction will be used to prepare the decoction needed for 2 days. Put the supplied herbal pack into an earthen pot or stainless steel pot, add 3840 ml of water and simmer under low flame until the volume is reduced to 480 ml. You will be requested to take a daily dose 120 ml of decoction before breakfast (6am) and before dinner (6pm) daily rest for the next day before breakfast (6am) and before dinner. (Measuring cup will be provided to measure the volume of water and

decoction.) Provided 2 pills will be requested to take along the decoction for rescue pain. Paththu will be given for the external application on Knee. One packet (50g) will be used for one day. Evenly applied paste over the knee it should be covered with a cotton wool and properly bandaged with a gauze bandage. Keep it for 8hrs and removed. Cleanse the knee area properly and the given two pottani will be steamed properly and dip in lightly heated mixture of 5ml oil from each Mee, Eradu, Thala, ethagithel and Pol thel and fomentation done for 30 min.

If you are selected for the group of Tablet Paracetamol and for external application topical formulation of 2% Diclofenac Sodium gel and fomentation with warm water before applying it and participants on rescue medication with oral Ibuprofen tablet

(b) You will be requested to take a daily dose of two tablets of Paracetamol (500mg) and two tablets of Ibuprofen (200mg) twice a day after breakfast and after dinner. 2% Diclofenac Sodium gel applied over knee and fomentation with warm water will be carried once a day.

Likewise pills with Decoction or two types of Tablets should be taken continuously for sixty days. Paththuna and Pottani or apply gel with hot water fomentation should be done continuously for 15 days. After that you will be presented to the hospital clinic two weekly, twice a month for three month and we will further examine about your disease condition.

You will be requested to visit the hospital clinic day before the starting research, 15th day after starting the research, 30th day, 45th day, day after finishing the research (61st day), 76th day,91st day,106th day, 121st day, 136th day,151st day. In each visit we analyse the disease condition and the activity of the medicines. During the visits we will analyse your disease condition and action of the medicines. Group of research team has prepared a questioner to collect information regarding the medicines given to you.

When you are visiting to hospital clinic on given dates please bring the empty packets of medicines. Qualified medical lab technician will drain 5ml of your blood before starting and after ending the research.

4. Potential benefits

Participation in this study may benefitted to you by getting a chance of involving a scientific research which determine the action of Ayurveda drugs. Participating a research will help to prevent health status of other citizens and your active contribution to your health to prevent your health status too.

5. Risks, hazards and discomforts

You will feel little discomfort while draining blood.

6. Reimbursements

There is no allocation of money from the budget for paid any sum of money for participating in this study. But you will be rewarded for transportation related to research, medicines and for investigation.

7. Confidentiality

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission.

8. Termination of study participation

You may stop participating in this study at any time (with no penalty or effect on medical care or loss of benefits). Please notify the investigator as soon as you decide to withdraw your consent.

9. Clarifications

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below.

Ayurveda Consultant Physician Dr.RHSK De Silva - 071 444 318

Ayurveda Consultant Physician Dr.PK Perera - 071 641 9072

Prof in Clinical Medicine Saroj Jayasinghe- 071 861 9331