JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM) UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG, SELANGOR, MALAYSIA.

FORM 2.4: RESPONDENT'S INFORMATION SHEET AND INFORMED CONSENT FORM

Please ***go through the following information carefully with your doctor and do not hesitate to discuss any questions you may have with the researcher.***

1. STUDY TITLE :

Evaluating the efficacy and safety of oral combination of alpha lipoic acid and vitamin B preparations in Carpal Tunnel Syndrome: a single center, randomized, double-blind, placebo-controlled trial.

2. INTRODUCTION:

You are invited to participate in this research study because of your carpal tunnel syndrome (CTS), that may benefit from pharmacological treatment. The treatment is with oral combination of alpha lipoic acid and vitamin B preparations. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your doctor with information on your health history, you might harm yourself if you are not being truthful with the information provided.

Your participation in this study is voluntary, you do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are

otherwise entitled. ***The investigators of this study will also be serving as your healthcare provider. As previously mentioned, this will not affect the delivery of treatment of your medical condition should you refuse to participate or withdraw from the study.***

This study has been approved by the University Ethics Committee for Research Involving Human Subject (JKEUPM). If you have any concerns regarding your rights as the study participant, including grievances and complaints, you may contact the JKEUPM.

3. WHAT WILL YOU HAVE TO DO?

- You are required to be present at the Neurology Clinic or Neurophysiology Laboratory in Hospital UPM for clinical examination and nerve conduction study (NCS).
- You will also be asked to fill in a series of questionnaires that would not take more than 5 minutes of your time.
- You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an *equal* chance of being placed in any group. You will receive either treatment or placebo.
- For the treatment group, you will receive oral tablet to be taken once daily for 6 months. The detailed procedure is also included on the medication package.
- For the placebo group, a similar tablet but without the active medication will be given for 6 months. There is no risk associated with the placebo beyond the risk that you may encounter in your daily life.
- The investigator and the sponsors of this study are not aware of the treatment allocation given to you as this is a blinded study.
- The follow-up will be conducted at 3 and 6 months. During these follow-up encounters, you will be examined again for resolution of clinical symptoms. You will also undergo another nerve conduction study to determine improvement of your symptoms. You will also be given another set of questionnaires to evaluate the symptoms post treatment.
- You are advised to continue taking medicines as normal and continue your follow up with your previous doctor for other concomitant illness. You will receive memo to notify their doctors about their participation in this study.

4. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

One who do not meet the inclusion criteria should not participate in the study. If you have underlying illness or psychological issue that hinder compliance and cooperation in this study, you are advised to discuss the matter with the investigators prior to participation.

5. WHAT WILL BE THE BENEFITS OF THE STUDY:

(a) TO YOU AS THE SUBJECT?

There may or may not be any benefits to you. Patients are informed that oral alpha lipoic acid and vitamin B combination is not intended to provide a cure for CTS and that reduction in symptoms may be modest. You will receive certification as appreciation and/or reimbursement

(b) TO THE INVESTIGATOR?

The information obtained from this study will help improve the treatment or management of other participants with the same disease or condition.

6. WHAT ARE THE POSSIBLE RISKS?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop the treatment. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study. You are covered with insurance in this study. They may trigger allergic reactions, and may also cause mild stomach upset, diarrhoea, or flatulence and bloating for the first few days after starting to take them. Some patients also complain of sleep disturbance and insomnia.

A last menstrual period (LMP) date will be obtained on potential women to conceive and patient must declare that they are not pregnant. Throughout this research, if you have the potential to get pregnant, it is very important that you practice effective pregnancy prevention

methods continuously and correctly. The research doctor will discuss with you about some family planning techniques. Tell your doctor as soon as possible, if you suspect that you are pregnant. If this happens, the treatment will be discontinued immediately and your participation in this research will be terminated.

Please ask your study doctor if you need more information on risks and side effects. The trial staff will inform you in a timely manner about any new findings or changes about the study product which may affect your health or willingness to continue in this study. Subjects will be informed if new information relevant to consent becomes available. Where necessary, you may be asked to re-consent to participate.

Overall, this study has minimal risk since the investigational product is considered as a safe supplement and has been used in clinical practice. All the procedures involved are considered a routine practice done for CTS patients. Active monitoring of adverse events will be conducted throughout the study.

7. WILL THE INFORMATION THAT YOU PROVIDE AND YOUR IDENTITY REMAIN CONFIDENTIAL?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor (UPM) or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary. Since this study will not reveal individual results, all the results will be kept confidential unless the subjects requested the result personally.

Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time. Publications and/or presentations that result from this study will not identify you by name. With your permission your family doctor will be informed of your participation in the study.

If you are interested in the results of the study, or any medical information obtained during the course of the study, these will be made available to you upon request. You are required to contact the PI or the study staffs for this matter.

8. WHO SHOULD YOU CONTACT IF YOU HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE RESEARCH?

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*Please initial here if you have read and understood the contents of this page*_____

9. CONSENT

I …… Identity Card No. …… address…… ……... ……..hereby voluntarily agree to take part in the research stated above *(clinical /drug trial/video recording/ focus group/interview-based/ questionnaire-based).

I have been informed about the nature of the research in terms of methodology, possible adverse effects and complications (as written in the Respondent's Information Sheet). I understand that I have the right to withdraw from this research at any time without giving any reason whatsoever. I also understand that this study is confidential and all information provided with regard to my identity will remain private and confidential.

I* wish / do not wish to know the results related to my participation in the research

I agree/do not agree that the images/photos/video recordings/voice recordings related to me be used in any form of publication or presentation (if applicable)

* delete where necessary

Signature ……..…… Signature ……..…….

(Respondent) (Witness)

Date :…….….. Name :…….…..

I/C No. :…….…..

I confirm that I have explained to the respondent the nature and purpose of the above-mentioned research.

Date ……..…… Signature ……..…….

(Researcher)