TITLE:

A STUDY TRIAL ON PROTESCAL IN PREVENTING POST CAESAREAN SECTION HYPERTROPHIC SCAR AND KELOID

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CO-RESEARCHER : DR. NOR AZILA MOHD NAFIAH

RESEARCH CODE : FF-2017-170

DATE : 26/4/2017

INFORMATION SHEET FOR PATIENT

RESEARCH TITLE

Study trial on protescal in preventing post caesarean section hypertrophic scar and keloid

INTRODUCTION

Hypertrophic scar and keloid following caesarean section has the potential to have a negative impact on overall quality of life, being a source of considerable distress, loss of self esteem and stigmatization due to the cosmetic imperfection. Till date, a lot of studies and clinical trial done with aims to prevent or to treat post operative hypertrophic scar and keloid.

PURPOSE OF RESEARCH

Through this study, we aim to prevent hypertrophic scar and keloid formation following caesarean section using Protescal gel.

HOW THE STUDY WILL BE DONE?

Women whom will undergo elective caesarean section that fulfill the study criteria are involved.

Before you agree to take part in the research, it is crucial for you to read and fully understand the information stated in this copy. If you are willing to participate, you will be requested to sign the consent form to confirm your participation.

Women that randomized to treatment group, Protescal will apply at uterine suture site, on rectus sheath and subcutaneous tissue layer prior to skin closure. Women that randomized to control group, will receive no protescal.

PARTICIPATION

This study is of voluntary basis and you have the right to withdraw at any time if you disagree to participate. Participation or not in this study will not affect the standard and quality of care provided to all patients. All data obtained will be recorded and will be used for analysis.

THE RISKS:

There is a no serious adverse reaction or side effect was reported following the used of Protescal.

THE BENEFITS:

There is unlikely to be a direct benefit for you in participating in this study. However, your participation could help us to measure the efficacy of Protescal in preventing post caesarean hypertrophic scar and keloid.

CONFIDENTIALITY:

The data from this study will be made into a report, which may be published. Access to the data is only by the research team and the REC UKM. The data will be reported in a collective manner with no reference to an individual. Hence your identity will be kept confidential. The participants have the right to know the outcome of this study.

PAYMENT AND COMPENSATION:

No extra charges or hidden cost will be incurred to participants. Similarly, participants will not be paid in this study.

QUERIES:

In case of any queries, you are always welcome to contact us.

Thank you for your cooperation.

DR. NOR AZILA MOHD NAFIAH
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WRITTEN PERMISSION FORM

I, _____ (IC Number: _____)

Agree / do not agree to participate in this research titled:

Protescal in preventing post caesarean section hyperthrophic scar and keloid

I have read and understood the contents of the research contents based on "Information to the Respondents" attached.

1. I understand that this research involves my health information.
2. I understand that all information given and all individual results are confidential and will be used for research purpose and for researcher's reference only.
3. I also understand that all information obtained may be used for publication but all personal details will not be disclosed.
4. I understand that this research is conducted to study the efficacy of Protescal in preventing post caesarean section hypertrophic scar and keloid.
5. I understand that I have the right to withdraw my participation and permission at any time needed, whenever I feel uncomfortable during any stage conducted by the researcher and no penalties could be placed on me.

…… ……..

(Patient's signature) (Witness signature)

Name: Name:

IC Number: IC Number:

Date: Date:

……

(Doctor's signature)

Name:

IC Number:

Date: