Ain Shams University
Faculty of Medicine
Ethical Committee of Scientific Research

Informed Consent From for Patients Invited to Participate in the Research

Research title: **NITROGLYCERINE SKIN PATCH VS PLACEBO PATCH FOR ENHANCING CERVICAL RIPENING IN LABOR INDUCTION: A RANDOMIZED CONTROLLED TRIAL**

Introduction and Aim of the Work:

Induction of labor is one of the most commonly carried out procedures in obstetrics and degree of cervical ripening is the major determinant of success of induction of labor. An ideal agent for cervical ripening is one that produces cervical ripening without uterine contractions or any adverse effect on the mother or fetus. Studies have shown that nitric oxide (NO) is the final common pathway in cervical ripening. In contrast to prostaglandins, these drugs are uterine relaxants and thus have the theoretical advantage of achieving cervical ripening without uterine contractions. This study aims to compare the efficacy of nitroglycerin skin patch as a NO donor versus placebo in addition to dinoprostone for improving the outcome of labor induction.

Place of Work:

The study will be carried out in Ain-Shams University Maternity Hospitals.

Number and Selection of Participants:

The study will include 100 pregnant women at term who will be indicated for induction of labor. They will be considered eligible for participation according to the inclusion and exclusion criteria for safety of the mother and the fetus.

Plan of Work:

The women who fulfill the inclusion criteria will undergo a thorough assessment and evaluation by detailed history, general and obstetric examination. After having an informed consent and fully explained steps of the research, they will be randomized into two groups to receive either nitroglycerine skin patch (Nitroderm TTS® 5mg, Novartis) or a placebo patch in combination with a well-established method of labor induction by (Dinoglandin® 3gm, Rotabiogen).

Benefits Expected to Participants:

The participants will be under close observation during the process of labor induction to ensure the safety of the mother and the fetus.

Benefits to Community:

The study aims to enhance success rate of labor induction and decreasing the rate of cesarean sections.

Risk and Complications

The patients will be monitored and will not be exposed to any considerable risk. The intervention drugs are approved for medical use with minimal side effects that will be controlled during the study.

Compensation in case of complications:

Both drugs: (Nitroderm TTS® 5mg, Novartis) and (Dinoglandin® 3gm, Rotabiogen) are licensed to use, hence no health insurance is needed, yet in case of occurrence of any complication, they will be managed according to *Standard Protocol of Risks* of Ain Shams University Hospitals.

Alternatives to participating

In case of refusing to participate in this research, the participant wishes will be respected and managed according to standard labor induction protocol of Ain-Shams Maternity Hospital.

Confidentiality

Participants' information will be in complete confidentiality, and no one has right to read your patient medical information except the main researcher and his co-workers.

Right to refuse or withdraw

Any participant doesn't have to take part in this research if she doesn't want. They may also stop participating at any time without declaring cause or suffering any negative consequences or penalty.

Contact information

Questions, concerns, or complaints: if you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the investigator:

Prof. Dr Abdel-Megeeed Ismail Abdel-Megeed 01001406366

Dr. Ahmed Sherif Abd El-Hamid at Mobile number:01227960980 .

You can also call Dr. Peter Nagy Aziz Hanna at mobile number: 01114834934

Participants Consent Approving Volunteering in a Study

Nitroglycerin Skin Patch for Facilitating Cervical Ripening: A Randomized Controlled Trial

Kindly Encircle Yes or No, knowing that this signifies your understanding of the nature of the study and any related subsequent problem

Patient's Random No.:

Patient's Initials:

- I have read the accompanied explanatory leaflet **YES NO**
- I can withdraw from the study any time **YES NO**
- I know that withdrawal from the study –in case of its occurrence- would not negative effects on health care provided to me. **YES NO**
- I have got enough time to ask about any issue. **YES NO**
- I agree to participate in this study **YES NO**

Name of the Student: **Signature:**

Name of the Researcher: **Signature:**

Date: