Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for parents or guardians of patients who are invited to participate in the research

Research title: The Effect of Periurethral Injection of Platelet Rich Plasma Versus Mid-Urethral Sling in Treatment of Stress Urinary Incontinence: A Randomized Clinical Trial.

Introduction and aim of the work:

Urinary incontinence can impact women's social, physical, mental and sexual wellbeing, and lead to depression and social isolation. According to the International Continence Society, stress urinary incontinence (SUI) is defined as a complaint of urinary incontinence due to increased abdominal pressure, such as exercise, laughing, sneezing, and coughing.

The aim of the present study is to evaluate the efficacy and safety of PRP in management of women with stress urinary incontinence in comparison to transobturator tape.

Place of work:

Gynecology and Obstetrics Hospital Medicine Department, Ain Shams University Hospital.

Number and Selection of participants:

- Will be 42 participants, (21) patients will receive periurethral PRP injection and (21) patients will receive a standard transobturator tape.

Plan of the work:

After your consent achievement and fully explained about the steps of research, the subjects of both groups will be subjected to the following:

1. Clinical parameters:

Complete history taking and thorough clinical examination

2. Laboratory parameters:

1. CBC.
2. Urine analysis.
3. Urodynamic test.

The patients' responses to the treatments will be evaluated one and three months after the treatments, using ICIQ questionnaire, and cough stress test.

Benefits expected from the study:

Benefits to the participants:

Relieve of stress urinary incontinence symptoms.

Benefits to the community:

To standardize the use of PRP which is less invasive in treatment of SUI.

Conducting the consent:

The consent will be conducted to the legal guardian or the patient by the investigator, Doctor Nahla fathy Abdelsamea elsebai khatab in the obstetrics and gynecology Department, Ain Shams University Hospital. Literate individuals will be left to read the consent followed by its

explanation by the mentioned investigator, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

This research will not expose your patient to further risks or complications despite the standard risks of protocol of Ain Shams University hospitals.

Alternatives to participating:

In case of refusing to participate in this research, your patient will be followed up and will receive his treatment as planned.

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the research is complete, you will be informed regarding your patient `s research results and also further information regarding your patient `s health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at anytime. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient's participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

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, Nahla fathy khatab at mobile number: 01030241711. If you have any problems or concerns about the study.

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my patient`s medical care.

- Name of participant:
- Signature of legal guardian:
- Or participant:
- Identity number or finger print: …….
- Date:

I have accurately read or witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher: Nahla fathy abdelsamea Elsebai khatab
- Signature of researcher:
- Date:

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is a committee whose task is to make sure that research participants are protected from harm.

If you wish to find more about Ethical Committee of Scientific research. Contact:

Name:

Address: Telephone number: