Azienda Ospedaliera Universitaria Federico II
Integrata con il Servizio Sanitario Regionale

DIPARTIMENTO AD ATTIVITÀ INTEGRATA MATERNO INFANTILE
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Title: Incidence of intrauterine adhesions following myomectomies with the use of an intrauterine anti-adhesion gel

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INFORMED CONSENT FOR PARTICIPATION IN A CLINICAL STUDY ON THE APPLICATION OF INTRAUTERINE GEL AFTER MYOMECTOMY

Dear Madam,

We kindly ask you to read this document carefully, which aims to inform you about your participation in a clinical study concerning the application of an intrauterine gel at the end of your myomectomy surgery.
Your participation in this study is voluntary. Before deciding, it is important that you understand the study's purpose, the procedures involved, the expected benefits, the potential risks, and your rights as a participant.

Please feel free to ask any questions to the medical staff to clarify any doubts before signing.

STUDY INFORMATION

This study aims to evaluate the effectiveness and safety of using an intrauterine gel to reduce the formation of intrauterine adhesions after myomectomy.

Study procedures:

- The study is **randomized**, meaning that a random process (similar to a lottery) will determine whether or not you receive the intrauterine gel.
- Two groups will be formed:
  - One group will receive the application of the intrauterine gel at the end of the surgery.
  - The other group will not receive the gel but will receive the standard post-surgical treatment.
- You will not be informed of the group to which you are assigned (**blinded study**), but all surgical and follow-up procedures will adhere to the same standard of care.
- Follow-up includes a control ultrasound after 1 month and an outpatient hysteroscopy after 3 months.
- Patients may be contacted for up to 24 months to assess their reproductive outcomes.

Study duration:
The study includes a post-operative observation period with regular follow-up visits to monitor for any complications and evaluate the results.

GEL APPLICATION PROCEDURE

If you are assigned to the treatment group, the intrauterine gel will be applied directly into the uterine cavity at the end of the surgical procedure under sterile conditions. The gel is a sterile, absorbable medical device that acts as a temporary barrier to reduce the risk of adhesions.

If you are assigned to the control group, the treatment will follow standard procedures without the application of the gel.

BENEFITS AND OBJECTIVES

Your participation will contribute to:

1. Evaluating whether the use of the intrauterine gel reduces the formation of post-operative adhesions.
2. Improving the quality of future care for women undergoing myomectomy.

There is no guarantee that you will receive direct personal benefits from participating in this study, but the results may enhance medical knowledge and the management of similar cases in the future.

RISKS AND POSSIBLE SIDE EFFECTS

The risks associated with participation include:

• **For the group receiving intrauterine gel:**

1. **Local and irritative reactions**

   • Pelvic or abdominal pain
   • Feeling of bloating or abdominal distension
   • Local irritation or inflammation (in some cases, a transient inflammatory response may occur)

2. **Allergic or hypersensitivity reactions**

• Itching, redness, or skin rash
• Localized or generalized swelling (angioedema, very rare)
• Anaphylactic shock (an exceptional event, but possible in individuals allergic to components of the gel)

3. **Infections and post-operative complications**

• Endometritis (infection of the endometrium)
• Fever and signs of pelvic infection
• Increased abnormal vaginal discharge (a sign of infection or inflammatory reaction)

4. **Systemic or general reactions**

• Nausea and general discomfort
• Temporary increase in white blood cells (leukocytosis), indicative of an inflammatory response
• Short-lasting febrile reactions

5. **Formation of seromas or fluid collections**

• Possible accumulation of fluid in the uterine or pelvic cavity, with a risk of delayed healing

• **For both groups:**
o Any complications related to the surgical procedure itself.

In case of unusual symptoms (pain, fever, abnormal discharge), it is essential to promptly inform your healthcare provider.

PARTICIPANT RIGHTS

- Participation is **voluntary**, and you may withdraw your consent at any time without affecting the quality of care you will receive.
- The randomization process is impartial and cannot be altered.

DATA CONFIDENTIALITY

All personal and clinical data collected will be treated anonymously and in compliance with current data protection regulations (e.g., GDPR in the European Union). Study results will be used solely for scientific purposes and will not allow participants to be directly identified.

INSURANCE CERTIFICATE
As this is an interventional study, an insurance certificate is required. This certificate will be attached to the present informed consent form, as mandated by the National Coordination Center of Ethics Committees.

CONSENT DECLARATION

I declare that I have been informed clearly and comprehensibly about:

- The nature and objectives of the study;
- The procedures involved and the randomization process;
- The expected benefits, potential risks, and available alternatives;
- My right to withdraw consent at any time.

I agree to participate in the study and authorize the possible application of the intrauterine gel if assigned to the treatment group.

Patient's signature: _____
Name (in block letters): _____
Date: _____

Physician's signature: _____
Name (in block letters): _____
Date: _____

Final Note

This document must also be adapted to local regulations and approved by the competent Ethics Committee.