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Informed Consent Form

OFFICIAL TITLE: Secondary Intention Wound Healing, in Patients Subjected to Surgical Resection of Pilonidal Cyst, Using Alginate Dressings With Silver and High-G Cellulose, Compared to the Use of Simple Gauze Dressings: Examination of the Quality of Life.

BRIEF TITLE: Alginate Dressings Versus Gauge Dressings After Pilonidal Cyst Resection: Examination of the Quality of Life

UNIQUE PROTOCOL ID: Pilonidal QoL
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Principal Investigator:
Ioannis Mamaloudis
Telephone: 00306977787592
Email: imamaloudis@yahoo.gr

Sub-Investigators:
Konstantinos Perivoliotis
Christos Zlatanos
Evangelia Kouvata

Study Director
Konstantinos Tepetes, Professor of General Surgery
Telephone: 00302413502804
Email: tepetesk@gmail.com

Department of Surgery
University Hospital of Larissa
Mezourlo 41110 Larissa
Greece

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Research Protocol: **Secondary Intention Wound Healing, in Patients Subjected to Surgical Resection of Pilonidal Cyst, Using Alginate Dressings With Silver and High-G Cellulose, Compared to the Use of Simple Gauze Dressings: Examination of the Quality of Life.**

1.Purpose of the trial

The purpose of this study is to compare the application of alginate dressings with silver and high-G cellulose and the use of simple gauge dressings in patients submitted to surgical resection of pilonidal cyst. The present trial will focus on the postoperative quality of life during the secondary intention wound healing.

2.Procedure

Participants will be admitted in the Department of Surgery of the University Hospital of Larissa in order to be operated for pilonidal cyst. Randomly, each patient will be allocated to one treatment group. In the first group Alginate dressings with silver and high-G cellulose will be applied to the wound, while in the second group, simple gauze dressings will be used. Postoperatively, the patient will be hospitalized in the clinic. On both patient groups the same surgical procedure will be performed. The pathological region will be resected, with the use of a scalpel and then hemostasis will be performed with diathermy. The patient will be discharged from the hospital directly postoperatively provided that no major hemorrhage will be present. Wound care will be performed in a specific way each time that the dressings will be removed. The wound will be irrigated with normal saline and betadine solution and finally without pressure the trauma will be dried. Photographic evidence will be taken each week to record the healing process. Maximum follow up will be 1 year.

3.Hazards and Adverse effects

Possible adverse effects include contamination, erythema and haematoma at the operative site. Other complications that may occur include recurrence of the disease or delayed healing. Nevertheless, providence for the treatment of complications has been included.

4.Expected Benefits

The resulting data will help to determine the effect of alginate dressings on the secondary wound healing rate and the quality of life after pilonidal cyst resection.

5.Publication of Data

The participation in this research project implies that you consent to the future publication of the trial results, provided that this information will be anonymous and the individual data of each participant will not be disclosed. The data that will be collected, will be encoded with a serial number and as a result, your name will not appear anywhere.

6.Information

Do not hesitate to ask questions about the purpose or the procedure of the trial. If you have any doubt or question, please ask us for further information.

7.Consent

Your participation in this trial is voluntary. You are free not to consent, or terminate your participation whenever you wish.

8.Informed Consent

I read this form and I understand the procedures that I will follow. I agree to participate in this research trial.

Date: __/__/__

Participant Name and Signature

Investigator Signature

Principal Investigator:
Ioannis Mamaloudis
Telephone: 00306977787592
Email: imamaloudis@yahoo.gr
Study Director
Tepetes Konstantinos, Professor of General Surgery
Telephone: 00302413502804
Email: tepetesk@gmail.com