Role for Fibrin Glue (Sealant) in Seroma Reduction After Inguinal Lymphadenectomy; A Randomized Controlled Trial

NCT04666051

30 October 2020

Study Protocol

Clinical background

Seroma is one of the most frequent complications occurring after ILND as it affects nearly one third of these cases. During the past decades, many actions have been tried in the perioperative care to decrease the incidence of these complications, as employing well vascularized bulky flaps to obliterate the dead space and to protect vessels, great saphenous vein sparing, strict bed rest and fibrin sealant application.

Objective

This study aimed to evaluate the role and impact of using fibrin glue to decrease seroma formation in patients undergoing inguinal lymph node dissection.

Study design:

Thirty-nine patients scheduled to perform Inguinal lymphadenectomy for various causes have been checked for eligibility to be enrolled in this prospective, randomized study.

Methods

Procedure

Inguinal lymphadenectomy is planned to be performed including scarifying saphenous vein with sartorius muscle transposition flap for protection of femoral vessels, then insertion of non-suction tube drain. All the previous steps to be performed similarly in both groups. At this stage, the wound is closed for the control group, while fibrin glue is prepared to be applied to the fibrin glue group in a dose of 2mL for 100 cm2 surface area. Postoperatively, the daily collected drain fluid is measured till the drain is removed when the daily drainage was less than 30 ml. The patients is planned to be followed up postoperatively for at least 4 weeks, to detect the possible clinically encountered complications as seroma, wound infection, or skin flap necrosis.

Data collection

Patients' demographic data and preexisting co-morbidities is recorded. Operative and pathological data regarding defect size, blood transfusion, primary tumor pathology, and number and status of retrieved lymph nodes is collected. The occurrence of post-operative seroma was the primary outcome. Other non serious adverse effect as hematoma, infection, or skin flap necrosis were recorded and compared between the two groups.

Statistical analysis:

The normality of distribution of variables is verified by Kolmogorov- Smirnov test. Chi-square test (Fisher or Monte Carlo) is used for comparisons between groups for categorical variables. Student t-test was used to compare two groups for normally distributed quantitative variables. For not normally distributed quantitative variables, Mann Whitney test was used to compare between two groups. P value was set to be significant if <0.05.