Official Title of the Study:

Umbilical Trocar Site Is the Usual Suspect for Trocar Hernia After Laparoscopic Cholecystectomy: A Prospective Study

NCT Number:

Not yet assigned (or your actual NCT number if assigned)

Document Type:

Informed Consent Form (ICF)

Document Date:

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INFORMED CONSENT FORM

Study Title:

"Investigation of the Effect of Gallbladder Extraction Site on Trocar Site Hernia Development After Laparoscopic Cholecystectomy"

Institution Conducting the Study:

University of Health Sciences, Ümraniye Training and Research Hospital, Department of General Surgery

Principal Investigator:

Assoc. Prof. Dr. Tolga Canbak

Contact: tolgacnbk@gmail.com

Purpose of the Study:

This study aims to investigate whether the site from which the gallbladder is extracted (either through the umbilicus or the upper abdomen) during laparoscopic gallbladder surgery affects the risk of developing a hernia after the operation.

Study Method:

Patients participating in this study will be randomly assigned (by chance) to one of two groups during surgery:

Group 1: Gallbladder will be extracted through the umbilicus

Group 2: Gallbladder will be extracted through the upper abdominal wall (epigastric site)

The surgical technique will be the same for both groups; only the extraction site will differ. This variation will not alter your treatment or surgical safety and will pose no additional risk.

What Will Be Asked of You:

Routine preoperative and postoperative examinations and tests will be conducted.

Your pain level will be assessed at 6 and 24 hours postoperatively using a 0–10 scale.

At the 12th month after surgery, an ultrasound will be performed to check for hernia development.

Potential Risks and Discomforts:

This study is not expected to introduce any additional surgical risk. The techniques used are standard

surgical procedures and will be performed by experienced surgeons.

Potential Benefits:

By participating in this study, you may help contribute to the identification of safer surgical practices for future patients undergoing similar procedures.

Confidentiality:

All your personal data will be kept confidential, and your identity will not be shared in any context. Study results may be shared in scientific settings, but no personal identifying information will be disclosed.

Voluntary Participation:

Your participation in this study is entirely voluntary. You have the right to decline participation or withdraw at any time. Your decision will not affect your medical care in any way.

Contact Information:

If you have any questions or concerns regarding this study, you may contact:

Assoc. Prof. Dr. Tolga Canbak – Department of General Surgery

Email: tolgacnbk@gmail.com

CONSENT DECLARATION:

I have read and understood the purpose, methods, possible risks, and benefits of this study. I have asked my questions and received satisfactory answers. I voluntarily agree to participate in this study.

Full Name: .....

Signature: .....

Date: ..... / ..... / .....