

Official Title:

Evaluation of the Effects of Subspinal Le Fort and Conventional Le Fort I Osteotomy on Nasolabial Soft Tissues

NCTNumber:

NCTXXXXXXXXX

Not yet assigned

Document Date:

January 2021

DocumentType:

Study Protocol

Statistical Analysis Plan

INFORMED CONSENT FORM (ICF)

Information Section

The study entitled “Evaluation of the Effects of Subspinal Le Fort and Conventional Le Fort I Osteotomy on Nasolabial Soft Tissues ” will be conducted by Assoc. Prof. Dr. Ahmet Emin Demirbaş.

The aim of this study is to investigate the indirect effects of osteotomy on nasal hard and soft tissues, as well as the amount of bleeding and edema associated with the surgical technique used during maxillary incision in patients who have undergone orthognathic surgery at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Erciyes University.

Within the scope of this study, the indirect effects of the conventional osteotomy technique used in Le Fort I osteotomy on nasal hard and soft tissues will be evaluated (by determining anatomical landmarks and angles), and its advantages and disadvantages will be compared. Patients’ nasal obstruction and aesthetic expectations will be assessed subjectively using the ROE (Rhinoplasty Outcome Evaluation) scale.

The data obtained from this study will be analyzed and may be published if deemed appropriate. During publication, no personal information identifying you will be shared with third parties.

Participation in this study is entirely voluntary. You are free to refuse participation or withdraw from the study at any time without any penalty, loss of rights, or negative impact on your treatment.

Contact information during the study:

Dt. Selin Çelebi

Tel: +90 554 572 20 59

Consent Section

“I have read and understood all the information provided in the Informed Consent Form. I have received both written and verbal explanations about the purpose and scope of the study from the person named below.

I understand that my participation in this study is voluntary, that I may withdraw from the study at any time with or without providing a reason, and that I may also be withdrawn from the study by the researcher regardless of my consent.

I voluntarily consent to the use of my personal and radiological data obtained within the scope of the study entitled ‘Evaluation of the Effects of Subspinal Le Fort and Conventional Le Fort I Osteotomy on Nasolabial Soft Tissues ’ solely for this study / for all future studies planned.

I agree to participate in this study of my own free will, without any coercion or pressure.”

Name and Surname of the Volunteer:

Signature:

Date:

Name and Surname of the Person Providing Information:

Signature:

Date:

Name and Surname of the Witness (if required):

Signature:

Date:

Name and Surname of the Legal Representative (if required):

Signature:

Date: