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Comparison of Birdflap, Winograd, and Noel surgical techniques in ingrowing nail surgery

Submission date
17/03/2025

Recruitment status
No longer recruiting

Registration date
20/03/2025

Overall study status
Completed

Last Edited
19/03/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to determine the most appropriate surgical method for patients presenting to the hospital with ingrown toenails. The study involves three different levels of nail bed resection and the outcomes of each resection level will be compared. Through this comparison, the aim is to identify the most effective surgical approach for ingrown toenail treatment.

Who can participate?
Patients aged between 18 and 65 years who have been diagnosed with ingrown toenails growing into the surrounding tissue

What does the study involve?
This study involves a surgical intervention. Participants are randomly allocated to one of three different surgical procedures and their outcomes will be compared.

What are the possible benefits and risks of participating?
Participation in this study offers several benefits for the participants. Surgical techniques for ingrown toenails that are claimed to be superior in the literature will be tested and compared. All patients will be closely monitored and recorded. In case of any complaints, they will have direct access to a physician. The worst possible outcome of this procedure is the risk of recurrence, which is a known risk in all surgical methods for ingrown toenails. If recurrence occurs, the necessary intervention will be promptly performed.

Where is the study run from?
Kutahya Health Sciences University School of Medicine Orthopaedic and Traumatology Department (Türkiye)

When is the study starting and how long is it expected to run for?
February 2025 to January 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Bilgehan Ocak, bilgeocak@gmail.com, bilgehan.ocak@ksbu.edu.tr

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06862232

Protocol serial number
6862232

Study information

Scientific Title
Comparison of outcomes of Birdflap, Winograd, and Noel surgical techniques in patients with ingrowing nails: a prospective randomized controlled study

Acronym
ITN

Study objectives
Null Hypothesis (H0):
In patients with ingrown nails, there is no significant functional difference between the Bird Flap surgical treatment and other surgical methods.

Alternative Hypothesis (H1):
In patients with ingrown nails, the Bird Flap surgical treatment is superior to the Winograd and Noel surgical techniques, demonstrating statistically significant differences in terms of wound healing, wound bleeding, infection rate, recurrence rate, and early return to social activities.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/02/2025, T.C. Saglık Bakanlıgı Eskisehir Sehir Hastanesi Klinik Araştırmalar Etik Kurulu (Republic of Turkey Ministry of Health Eskişehir City Hospital Clinical Research Ethics Committee) (71 Evler Mah. Çavdarlar Sok. 26080 Odunpazarı/Eskisehir/Türkiye, Eskisehir, 26080, Türkiye; +90 (0)2226114000; eskisehirsh.etik@saglik.gov.tr), ref: KAEK-09-24/62

Study design
Prospective randomized study

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Surgical treatment of ingrown toenail

Interventions
The study is designed as a parallel-group, randomized controlled trial, consisting of three independent groups, each undergoing a different surgical technique for the treatment of medially ingrown toenails. Patients will be assigned to one of the three groups using a pre-generated randomized allocation list, ensuring an unbiased distribution. Each group will receive only the designated surgical intervention, with no crossover between groups.

The surgical procedures will be performed according to the assigned technique, and postoperative outcomes - including recurrence rates, complications, pain levels, and functional recovery - will be assessed by an independent, blinded evaluator, ensuring objectivity and minimizing potential bias in outcome assessment.

Modified Winograd “Bird Flap” Technique:
Modified Winograd “Bird Flap” Technique In the first group (n = 36), the modified Winograd “Bird Flap” technique will be performed. Local anesthesia will be administered using a 1% lidocaine solution, applied at the base of the first toe, and a temporary tourniquet will be placed using a sterile glove. The procedure involves creating an incision resembling the contour of a sparrow’s body, extending over the lateral nail bed and reaching the proximal germinal matrix and underlying bone tissue. The granulated and infected tissue will be excised entirely to ensure complete removal of the affected area. The wound will then be sutured using 3/0 prolene sutures to achieve optimal wound closure. This technique aims to preserve the nail bed while effectively addressing the recurrence risk associated with conventional Winograd procedures.

Modified Noel Technique:
Modified Noel Technique In the second group (n=36), the modified Noel technique will be utilized. Following local anesthesia with 1% lidocaine solution and the application of a temporary tourniquet, an approximately 4-6 mm semi-elliptical incision will be made adjacent to the lateral borders of the nail bed to access the granulated tissue. Unlike the Bird Flap technique, this method preserves both the nail bed and the proximal germinal matrix, ensuring that only the inflamed soft tissue and granulated tissue are excised. The remaining tissue will be sutured subungually using 3/0 prolene sutures to facilitate proper healing and maintain the structural integrity of the nail. This technique is designed to minimize invasiveness while effectively managing infected and inflamed tissue.

Classic Winograd Technique:
Classic Winograd Technique In the third group (n = 36), the classic Winograd technique, a widely used traditional surgical approach, will be performed. After administering 1% lidocaine solution for local anesthesia and applying a temporary tourniquet, a linear incision will be made to separate the nail bed from the soft tissue. The lateral edge of the nail bed and the germinal matrix will then be excised in a linear fashion, ensuring complete removal of the affected nail portion. The wound will subsequently be sutured using 3/0 prolene sutures. This method has been a standard approach for ingrown toenail surgery and is associated with high recurrence prevention rates but also carries a risk of cosmetic and structural alterations in the nail.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Reccurence: the regrowth of the toenail towards the skin and/or soft tissue, leading to the recurrence of preoperative symptoms, characterized by pain, inflammation, and discomfort, occurring at any time within the first 6 months postoperatively.

Key secondary outcome(s))
1. Recovery time: time to resume wearing normal footwear and return to work duration, measured at 6 months
2. Complication: severe pain, infection, bleeding, or wound care complications requiring hospital or physician intervention at 6 months
3. Pain, functional status, and quality of life assessed using the EuroQol 5-Dimension 5-Level Scale (EQ-5D-5L) at 1, 2, 3 and 6 month follow-ups

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Age between 18 and 65 years
2. Diagnosis of ingrown toenail (onychocryptosis)
3. Indication for surgical treatment

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Presence of malignancy in the body
2. Existence of foot deformities
3. Presence of pincer nail deformity
4. History of drug allergy
5. Presence of active infection in the body
6. Diabetic neuropathy or necrotic foot ulcers
7. Pregnancy
8. History of prior foot or ankle surgery

Date of first enrolment
01/03/2025

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
Türkiye

Study participating centre
Kütahya City Hospital
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43040

Sponsor information

Organisation
Kutahya Saglik Bilimleri Universitesi

ROR
https://ror.org/01fxqs415

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Dr Bilgehan Ocak (bilgeocak@gmail.com)

IPD sharing plan summary
Stored in non-publicly available repository, Available on request