Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effectiveness of platelet-rich fibrin on reducing complications after total thyroidectomy surgeries

Protocol summary

Study aim
To determine the effectiveness of Platelet-Rich Fibrin(PRF) in reducing postoperative complications following total thyroidectomy surgeries

Design
A single-center, randomized, double-blind, parallel-group trial. Participants (N=44) are allocated to either the PRF intervention or saline control group using block randomization with a fixed block size of four generated by Excel.

Settings and conduct
The trial will be conducted at Amir A'lam Hospital. An unblinded clerk, not involved in treatment/follow-up, will manage the randomization list and inform the independent PRF injection technician of the group assignment. The operating surgeon, outcome assessors, investigators, and patients will be blinded to the group allocation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients over 18 who are candidates for total thyroidectomy No history of neck surgery Normal preoperative calcium levels Exclusion Criteria: Coagulation disorders Use of therapeutic-dose anticoagulant medications(except for prophylaxis) Known sensitivity to any of the components of PRP and fibrin History of radiotherapy or extensive surgery in the neck region Presence of active infection or advanced malignancy with metastasis

Intervention groups
- Intervention Group(Platelet-Rich Fibrin): Injection of Injectable Platelet-Rich Fibrin(i-PRF) during the surgery into the surgical bed prior to suturing, and placement of Concentrated Platelet-Rich Fibrin(C-PRF) in the surgical bed. - Control Group(Standard): Standard surgical procedure without the use of Platelet-Rich Fibrin(using only normal saline injection).

Main outcome variables
Scar assessment using the Patient and Observer Scar Assessment Scale and the Vancouver Scar Scale, Postoperative drainage volume and duration, hypocalcemia, Patient satisfaction with scar appearance measured by the Visual Analogue Scale, and Duration of hospital stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251118068031N1**
Registration date: **2025-12-25, 1404/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-25, 1404/10/04**
Update count: **0**

Registration date
2025-12-25, 1404/10/04

Registrant information

Name
Maryam Namjoomoghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-12-21, 1404/09/30

Expected recruitment end date
2027-03-20, 1405/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of platelet-rich fibrin on reducing complications after total thyroidectomy surgeries

Public title
Evaluation of the effectiveness of platelet-rich fibrin on reducing complications after total thyroidectomy surgeries
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for total thyroidectomy over 18 years of age No history of neck surgery Normal preoperative calcium levels
Exclusion criteria:
Coagulation disorders Use of therapeutic-dose anticoagulant medications(except for prophylaxis) Known sensitivity to any of the components of PRP or fibrin History of radiotherapy or extensive surgery in the neck region Presence of active infection or advanced malignancy with metastasis
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
We will use block randomization at the individual level. A random sequence will be generated using a computer-generated list of random binary numbers in Microsoft Excel, with a fixed block size of four. In total, 11 blocks of four will be created, each containing 2 participants in the case group(assigned the number 1) and 2 participants in the control group(assigned the number 0). Eligible surgical patients will be assigned to these blocks according to their surgical order upon admission. The allocation sequence will be managed by a secretary who is not involved in the clinical evaluations and is aware of the group assignments. This secretary will be responsible for assigning participants based on the predetermined random list.
Blinding (investigator's opinion)
Double blinded
Blinding description
To ensure blinding, outcome assessors, researchers, and patients will be kept unaware of group assignments(double-blind). Only the Platelet-Rich Fibrin(PRF) injection technician will be informed about the patient assignments. The PRF injection team will be independent from the surgical team. Consequently, the operating surgeon will have no knowledge of group allocations, preserving blinding integrity for the surgical team and other involved personnel. The PRF injection technician will administer PRF in the case group and inject normal saline using the same method and equipment as the PRF injection as a placebo in the control group. The technician performing the PRF injection cannot be blinded to the grouping due to the nature of the intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Amir A'lam Hospital Complex
Street address
Sa'adi street, Amir Alam Hospital
City
Tehran
Province
Tehran
Postal code
1145765111
Approval date
2025-10-20, 1404/07/28
Ethics committee reference number
IR.TUMS.AMIRALAM.REC.1404.039

Health conditions studied

1

Description of health condition studied
Surgical scar formation site after total thyroidectomy
ICD-10 code
L90.5
ICD-10 code description
Scar conditions and fibrosis of skin

2

Description of health condition studied
Postsurgical hematoma after total thyroidectomy
ICD-10 code

E89.810

ICD-10 code description

Postprocedural hemorrhage and hematoma of an endocrine system organ or structure following an endocrine system procedure

Primary outcomes

1

Description

postsurgical scar appearance following total thyroidectomy surgery

Timepoint

Immediately after surgery and 1,6 months after surgery

Method of measurement

The Patient and Observer Scar Assessment Scale , The Vancouver Scar Scale

2

Description

Patient satisfaction with scar appearance following total thyroidectomy surgery

Timepoint

Immediately after surgery and 1,6 months after surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Postoperative drainage duration

Timepoint

during recovery time

Method of measurement

Based on observation of the surgical site

2

Description

Postoperative drainage volume

Timepoint

during recovery time

Method of measurement

Based on observation of the surgical site

3

Description

Blood calcium level

Timepoint

Before surgery, 1,2 ,7 days after surgery and 1 month after surgery

Method of measurement

Free blood calcium level measured by lab

4

Description

Duration of Postoperative Hospitalization

Timepoint

At discharge

Method of measurement

Based on hospitalization documents

Intervention groups

1

Description

Intervention group: Injection of Injectable Platelet-Rich Fibrin(i-PRF) during the surgery into the surgical bed prior to suturing, and placement of Concentrated Platelet-Rich Fibrin(C-PRF) in the surgical bed.

Category

Prevention

2

Description

Control group: Standard surgical procedure without the use of Platelet-Rich Fibrin(PRF) (using only normal saline injection).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir A'lam Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Namjoo Moghadam
Position
Resident
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

1. De-identified Individual Participant Data This dataset contains all collected participant-level information from the clinical trial after the removal of all direct personal identifiers. The data to be shared includes: Patient demographics (age, sex). Patient allocation (intervention/treatment group assignment). Primary and secondary outcome measure data. Safety data, including reported adverse events. Data on protocol deviations. 2. Clinical Study Report This is a comprehensive summary of the full, formal Clinical Study Report. It will include detailed information on the study design, methodology, participant flow, statistical methods, results for all efficacy and safety outcomes, and a final conclusion. This document will be made publicly available.

When the data will become available and for how long

1. De-identified Individual Participant Data • Availability Start Date: This dataset will become available for request after the publication of the primary trial results in a peer-reviewed journal. • Period of Availability: The data will be made accessible indefinitely. 2. Clinical Study Report Synopsis • Availability Start Date: This document will be made publicly available concurrently with the publication of the primary results manuscript. • Period of Availability: It will be accessible indefinitely, hosted on the publishing journal's website according to their archiving policy.

To whom data/document is available

1. De-identified Individual Participant Data Access to the data is open to any qualified researcher who submits a valid request. 2. Clinical Study Report Synopsis Based on the publishing journal policies

Under which criteria data/document could be used

The shared data may be used for purposes of systematic review, meta-analysis, and independent validation of the original study findings. However, any re-analysis of the data intended for publication as a separate scientific article requires prior written approval from the study authors. Explicit permission is required for any use beyond these specified purposes.

From where data/document is obtainable

1. De-identified Individual Participant Data By submitting a formal request directly to the study's corresponding author via email. 2. Clinical Study Report Synopsis Directly accessible from the official online platform of the publishing journal.

What processes are involved for a request to access data/document

1. De-identified Individual Participant Data Upon receipt of a formal data request, approval will be sought from the funding body and the institutional research committee. Once all necessary approvals are secured, the de-identified dataset will be prepared and transferred securely to the requester. 2. Clinical Study Report Synopsis No formal request process is required for this document. The Clinical Study Report Synopsis will be made publicly available according to the publishing journal.

Comments