

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effects of Using a Hemostatic Focus Scalpel on Postoperative Complications of Thyroidectomy Compared to the Conventional Method: A Clinical Trial

Protocol summary

Study aim

This study is designed to compare the efficacy and safety of the Focus Harmonic Scalpel (HS) with the conventional clamp-and-tie technique (CT) in adult patients undergoing open thyroidectomy.

Design

This study is a prospective randomized clinical trial (RCT).

Settings and conduct

All surgeries will be performed by one surgeon at Afzalipour Hospital to ensure consistency. Both groups undergo standard open thyroidectomy; the only difference lies in the hemostasis method—Harmonic Scalpel (HS) versus conventional clamp-and-tie (CT). Nerve and parathyroid preservation, hemostasis verification, optional drain placement, and standard wound closure are performed in all cases.

Participants/Inclusion and exclusion criteria

The target population includes all adult patients (aged 18 years and older) who are candidates for open thyroidectomy— including hemithyroidectomy, near-total thyroidectomy, or total thyroidectomy— for the treatment of benign (e.g., multinodular goiter, toxic nodular goiter, Graves' disease) or malignant thyroid disorders at Afzalipour and Shahid Bahonar Hospitals in Kerman. Patients will be selected using a convenient sampling method.

Intervention groups

Open thyroidectomy will be performed in both groups, with the only difference being the method of hemostasis and division of thyroid vessels and tissue: one group using the conventional clamp-and-tie (CT) technique, and the other employing the Harmonic Scalpel (HS) method for hemostasis.

Main outcome variables

Duration of surgery Intraoperative blood loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260426069165N1**

Registration date: **2026-05-05, 1405/02/15**

Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**

Update count: **0**

Registration date

2026-05-05, 1405/02/15

Registrant information

Name

Ehsan Mahmoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 179 8724

Email address

s.em2012@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Using a Hemostatic Focus Scalpel on Postoperative Complications of Thyroidectomy Compared to the Conventional Method: A Clinical Trial

Public title

Comparison of the Effects of Using a Hemostatic Focus Scalpel on Postoperative Complications of Thyroidectomy Compared to the Conventional Method: A Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals aged 18 years or older Patients scheduled for primary open thyroidectomy (first-time thyroid surgery) Ability to understand the study and to sign a written informed consent form

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients, after signing the written informed consent form, will be allocated to one of the two study groups (HS group or CT group) using a block randomization method (randomized block design). Allocation concealment will be ensured through the use of sealed, opaque, numbered envelopes. The envelope corresponding to each patient will be opened immediately before the start of surgery, after final confirmation of the patient's eligibility, by a nurse who is not involved in the surgical procedure or outcome assessment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Kerman University of

Medical Sciences

Street address

Afzalipour hospital, Imam Khomeini Local Lane

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2026-01-07, 1404/10/17

Ethics committee reference number

IR.KMU.AH.REC.1404.216

Health conditions studied

1

Description of health condition studied

Hemostasis status in open thyroidectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of surgery

Timepoint

Time from skin incision to skin closure

Method of measurement

Surgical procedure description

2

Description

Intraoperative blood loss

Timepoint

end of the procedure

Method of measurement

Surgical procedure description

Secondary outcomes

1

Description

hypocalcemia

Timepoint

Postoperatively and at 6 months postoperatively

Method of measurement

Lab tests

2

Description

RLN paralysis

Timepoint

Postoperatively and at 6 months postoperatively

Method of measurement

Patient clinical record

3

Description

Postoperative hematoma

Timepoint

end of the procedure

Method of measurement

Patient clinical record

Intervention groups

1

Description

Intervention group: In this group, hemostasis of the thyroid vessels (superior, middle, and inferior thyroid arteries and veins) and division of the thyroid tissue will be performed using the **Focus Harmonic Scalpel** (Ethicon Endo-Surgery). The use of **sutures** or **electrocautery** will be minimized and applied only when necessary — for example, in cases of bleeding from vessels exceeding the device's sealing capacity or diffuse oozing.

Category

Treatment - Surgery

2

Description

Control group: In this group, the conventional hemostasis technique will be used. Major vessels will be clamped with surgical clamps and then ligated with absorbable suture material (such as 2-0 or 3-0 Vicryl) using the clamp-and-tie method. For control of bleeding from smaller vessels and the thyroid bed, monopolar or bipolar electrocautery may also be utilized.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Abouzar Pourrashidi

Street address

Imam Khomeini Local Lane

City

Kerman

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Kerman

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7616913555

Phone

+98 913 393 1624

Email

abz_pur@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abouzar Pourrashidi

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Email

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Abouzar Pourrashidi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Afzalipour hospital, Imam Khomeini Local Lane

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abouzar Pourrashidi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

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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

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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