# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)

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+98 913 179 8724

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s.em2012@yahoo.com

**Recruitment status**

**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
**Province**
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**Postal code**
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**
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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
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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

Abouzar Pourrashidi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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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