Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the Effectiveness of Superficial Cervical Plexus Block (SCPB) under Ultrasound-Guided and via Landmark-Based on Severity of Pain After Thyroidectomy

Protocol summary

Study aim

The effect of the Superficial Cervical Plexus Block under ultrasound guide and through anatomical landmarks on the severity of pain after Thyroidectomy

Design

A triple blinded clinical trial with a control group and two intervention groups, randomized by Random Allocation software on 102 patients undergone thyroidectomy in 2019.

Settings and conduct

After selecting and grouping patients referred to Bahonar Hospital in Kerman for thyroidectomy, the using of the Visual Analogue Scale will be taught to them. Then, general anesthesia will be done. In two groups 1 and 2, a superficial cervical plexus block will be done with ultrasound-guided or anatomical landmarks. After surgery, the peer reviewer evaluates the pain severity by using the VAS every 3 to 24 hours. In this study, the patient, the pain assessor and data analyzer, would not be aware of the patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Ages 18 To 65 Years, ASA Classes 1 And 2, Informed Consent; Exclusion Criteria: A History Of The Previous Thyroid, Parathyroid Or Neck Surgery, Retrosternal Goiter, Thyroid Dysfunction, Body Mass Index Above 25, Coagulation Disorders, Bupivacaine Sensitivity, Short Neck, Pathology Of The Injection Site, Narcotic Addiction

Intervention groups

Group 1: Superficial cervical plexus block under ultrasound guidance. Group 2: Superficial cervical plexus block through anatomical landmarks. Group 3: Non superficial cervical plexus block

Main outcome variables

The pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190611043861N1**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

Registration date

2019-07-02, 1398/04/11

Registrant information

Name

Sadra Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

s.samadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of Superficial Cervical Plexus Block (SCPB) under Ultrasound-Guided and via Landmark-Based on Severity of Pain After Thyroidectomy

Public title
Comparison of Superficial Cervical Plexus Block Methods on the Severity of Pain After Thyroidectomy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All Patients Candidates for Thyroidectomy Referred to Shahid Bahonar Hospital in Kerman, 2019

Exclusion criteria:
Age under 18 years Age over 65 years History of previous thyroid or parathyroid and neck surgery Retrosternal Goiter Thyroid dysfunction Urgent surgery within the first 24 hours Body Mass Index More Than 25 Coagulation Abnormalities Allergy to Bupivacain ASA Class above 2 Short Neck Pathology of Incision Site Patient Refusal Opioid Addiction

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple randomization method using "Random Allocation software" will be used. The sample size (102 people) and the number of groups (3 groups) are included in the software. Then, based on the software output, the patients after going to the hospital will be allocated in one of the three groups: block under Ultrasound-guided, via Landmark and control.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The patient is not aware of the grouping. After surgery, the pain assessor is not aware of the grouping. Data analyzer is not aware of the grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Someyah crossroad, Beginning of Jahad Blvd, Beginning of Ibn Sina Street, In Front of Besat Clinic

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2019-05-25, 1398/03/04

Ethics committee reference number
IR.KMU.REC.1398.135

Health conditions studied

1

Description of health condition studied
Thyroidectomy, Superficial Cervical Plexus Block

ICD-10 code
D34

ICD-10 code description
Benign neoplasm of thyroid gland

Primary outcomes

1

Description
Pain Score Based on Visual Analog Scale

Timepoint
Pain Severity Evaluation, Immediately Post Operation and 3, 6, 9, 12 and 24 Hours After Surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Total Postoperative Prescribed Opioid

Timepoint
First 24 Hours Post Operation

Method of measurement
Nursery Records

2

Description
Total prescribed opioids during surgery

Timepoint

From beginning of surgery until the completion

Method of measurement

Anesthesia records

Intervention groups

1

Description

First Intervention group: With the patient in supine position, the head turned slightly away from the side to be blocked. After prep the transducer is placed on the lateral neck, overlying the sternocleidomastoid muscle (SCM) at the level of its midpoint (approximately the level of the cricoid cartilage). Once the SCM is identified, the transducer is moved posteriorly until the tapering posterior edge is positioned in the middle of the screen. At this point, an attempt should be made to identify the brachial plexus and/or the interscalene groove between the anterior and middle scalene muscles. The plexus is visible as a small collection of hypoechoic nodules (honeycomb appearance) immediately underneath the prevertebral fascia that overlies the interscalene groove. Once identified, the needle is passed through the skin, platysma and prevertebral fascia, and the tip placed adjacent to the plexus. Following negative aspiration, 1 to 2 milliliter of Bupivacaine 0.25% is injected to confirm the proper injection site. Then the remainder of the local anesthetic (15 milliliters) is administered.

Category

Rehabilitation

2

Description

Second Intervention group: With the patient in supine position and the head turned slightly away from the side to be blocked, is asked to lift his or her head off of the bed to accentuate the sternocleidomastoid muscle. The needle insertion site is along the posterior border of the sternocleidomastoid. After prep three injections of 5 milliliters of Bupivacaine 0.25% are injected behind the posterior border of the sternocleidomastoid muscle subcutaneously, perpendicularly, cephalad, and caudad in a fan fashion.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Sadra Samadi

Street address

Shahid Bahonar Hospital, Qarani Street.

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http://www.kmu.ac.ir/fa/bh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

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Web page address

http://kmu.ac.ir/fa/vcrt

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

Sadra Samadi

Position
Anesthesiology Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All of the data can be shared after unidentifiable people.
When the data will become available and for how long
Start the access period 6 months after publishing the results
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Any analysis of the data is allowed but not published. A written request with a valid letter from a University or scientific institution with an identification card is required.
From where data/document is obtainable
Sadra Samadi
What processes are involved for a request to access data/document
A written request will be submitted to the research Vice-chancellor of the Kerman University of Medical Sciences with a valid letter from the University or institute.
Comments