

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparing the effect of Pulsed and Conventional Radiofrequency celiac plexus neurolysis on Abdominal Cancer Pain

Protocol summary

Summary

1)Goals: The aim of this double-blinded RCT is to compare the effect of conventional and pulsed-RF Celiac ganglion neurolysis on relieving pain in patients with abdominal cancer in order to find the most effective method in relieving pain in this group of patients. 2) Designing the study: This neurolytic block would be performed in patients after being randomly allocated into 2 groups. After taking informed consent from all patients, the block would be performed under fluoroscopy; in the conventional group after placing the needle on correct position, continuous RF would be used for two cycles of 90seconds, and in the pulsed-RF group two cycles of pulsed radiofrequency for 15 minutes are used. The visual analogue score, and the amount of daily used analgesic would be measured weekly for 3 consecutive months. 3) Technique: The patients will be randomly divided into two groups of CRF and PRF. In the conventional RF group, two cycles of 90 seconds and in the pulsed RF one, two cycles of 15 minutes would be used. 4) Follow up: After the procedure, the pain score according to VAS, and the amount of daily used analgesic are recorded in the questionnaire forms for 3 consecutive months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306307984N9**

Registration date: **2013-09-11, 1392/06/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-11, 1392/06/20

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences, Vice-chancellor for research

Expected recruitment start date

2012-05-08, 1391/02/19

Expected recruitment end date

2014-05-09, 1393/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Pulsed and Conventional Radiofrequency celiac plexus neurolysis on Abdominal Cancer Pain

Public title

Comparing the effect of Pulsed and Conventional Radiofrequency celiac plexus neurolysis on Abdominal Cancer Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age range of 20 to 60 years old ;

painful non-operable abdominal cancer Exclusion criteria:
Renal failure; Pregnancy; Allergy to Ropivacaine and
Opioid; Significant coexisting disease (CNS or
cardiovascular problems)

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical
sciences

Street address

Tehran University of Medical Sciences (TUMS), 4th
floor, Corner Ghods St., Keshavarz Blv, Tehran

City

Tehran

Postal code

1417653761

Approval date

2012-05-06, 1391/02/17

Ethics committee reference number

90-01-30-13002-42105

Health conditions studied

1

Description of health condition studied

Abdominal cancers

ICD-10 code

C25.0

ICD-10 code description

Malignant neoplasm of pancreas

Primary outcomes

1

Description

Visual analogue score according to the designed pain
ruler

Timepoint

Weekly for 3 consecutive months

Method of measurement

Visual analogue score is measured with a marked ladder
from 0 to 10

2

Description

The amount of analgesic used

Timepoint

Weekly for 3 consecutive months

Method of measurement

The percentage of the used analgesic is measured by
dividing the amount of analgesic after the block by the
amount before the block and then multiplying the result
by 100

Secondary outcomes

1

Description

Blood pressure changes

Timepoint

Before the intervention and 3 weeks thereafter

Method of measurement

Measured with digital sphygmomanometer

Intervention groups

1

Description

The patients are first divided into 2 groups each
containing 25 persons. In the first group or the PRF
group, celiac plexus block would be performed under
fluoroscopy and sterile condition after placing the patient
on prone position on the OR table. All the patients should
have IV line and pulse-oxymetry plus blood pressure and
ECG monitoring. The target point is on the anterolateral
part of the first lumbar vertebrae. After prep and drape
of the skin, a skin wheal would be made by injection of
Lidocaine 2 % (5 ml) into the subcutaneous tissues. The
C-arm will be placed in 30 degrees ipsilateral oblique
position and the 150 mm RF cannula with 10 mm active
tip will be introduced in tunnel vision towards the L1
vertebral body. In the lateral view the needle tip should
reach 1-2 centimeter in front of the L1 body. Then 2 ml
contrast media (Visipaque 270 mg/dl) would confirm the
correct position and 5 ml Ropivacaine 0.5 % (long-acting
local anesthetic) would be injected. Afterwards the
Radiofrequency waves in the pulsed mode at 42 degrees
and for two cycles of 15 minutes would be started with
an interval of 30 seconds between the two.

Category

Treatment - Other

2**Description**

In the second group the same method is used except for the final stage for which the conventional mode with RF cycles of 90 degrees and for 90 seconds will be used twice with an interval of 30 seconds. At the end of the procedure, the patients will be transferred to the recovery room and they will be discharged if no complication occurs after 2 hours

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Hazrat e Rasoul Hospital

Full name of responsible person

Dr Farnad Imani

Street address

Department of anesthesiology and pain Rasoul-Akram Medical Center, 4th floor, number 7, Niyayesh St, Sattar Khan Av

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran university of medical sciences, Vice-chancellor for research

Full name of responsible person

Dr Akhounzadeh

Street address

The Vice-chancellor for research of TUMS, 4th floor, the central building of TUMS, Ghods St., Keshavarz Boulevard, Tehran

City

Tehran

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, Vice-chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran university of medical sciences

Full name of responsible person

Dr Farnad Imani

Position

Associate professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty