

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Investigate prophylactic effect of Gabapantine on nausea and vomiting after excision and graft in patient with burn

Protocol summary

Summary

The current study as a double blind clinical trial will be conducted at Velayat hospital affiliated to guilan university of medical sciences. The aim of this study is to investigate the prophylactic effect of Gabapentin on nausea and vomiting after early excision and graft in patient with burn. A number of 116 patient will be randomly divided into two groups of Gabapentin and control. 2 hours before anesthesia, Gabapentin group will receive 600 mg of gabapentin orally. Anesthesia and surgery will be carried out according to the standard protocol. Nausea and vomiting frequency and severity will be measured at 5 point times (0,6,12,18 ,24). Finally the data will be analyzed and compared in 2 groups. Inclusion criteria: Age 18 to 60 years old; ASA I&II ;early surgical excision and graft in Burned patient Exclusion criteria: Addiction; smoker; alcoholic patient; use of antiemetic; anti acid; analgesic; anti depressant; ca Chanel blocker; renal and hepatic insufficiency; underlying disease leading to nausea and vomiting; pregnancy; lactating; allergy to gabapentin or opium and motion sickness

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100230072N2**

Registration date: **2017-05-09, 1396/02/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-09, 1396/02/19

Registrant information

Name

Siamak Rimaz

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 8540

Email address

smkrimaz@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

governmental

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate prophylactic effect of Gabapantine on nausea and vomiting after excision and graft in patient with burn

Public title

gabapentine effect on post operative nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 60 years old; ASA I&II ;early surgical excision and graft in Burned patient Exclusion criteria: Addiction; smoker; alcoholic patient; use of antiemetic; anti acid; analgesic; anti depressant; ca Chanel blocker; renal and hepatic insufficiency; underlying disease leading to nausea and vomiting;

pregnancy; lactating; allergy to gabapentin or opium and motion sickness

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **116**

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 Guilan University of Medical Sciences

Street address

Namjoo ave

City

Rasht

Postal code

4193833697

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.GUMS.REC.1395.113

Health conditions studied

1

Description of health condition studied

nausea and vomiting

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

nausea

Timepoint

PACU (T0) 6 hr post surgery (T1) 12 hr post surgery (T2) 18 hr post surgery (T3) 24 hr post surgery (T4)

Method of measurement

vas score

2

Description

vomitting

Timepoint

PACU (T0) 6 hr post surgery (T1) 12 hr post surgery (T2) 18 hr post surgery (T3) 24 hr post surgery (T4)

Method of measurement

frequency

Secondary outcomes

1

Description

pain

Timepoint

PACU (T0) 6 hr post surgery (T1) 12 hr post surgery (T2) 18 hr post surgery (T3) 24 hr post surgery (T4)

Method of measurement

vas

Intervention groups

1

Description

Intervention Group: Oral administration of Gabapantin 600 mg 2hours before anesthesia

Category

Prevention

2

Description

Control Group: No drug

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

anesthesia research center

Full name of responsible person

Dr Siamak Rimaz

Street address

Namjoo Avenue, Velaia hospital

City

rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Anesthesia research centre

Full name of responsible person

Dr. siamak Rimaz

Street address

Namjoo Avenue, Velaiat hospital

City

rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Anesthesia research centre

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

Guilan university of medical sciences

Full name of responsible person

Dr. Siamak Rimaz

Position

Assistant professor

Other areas of specialty/work

Street address

Namjoo Avenue, research centre, Velaiat hospital

City

rasht

Postal code

Phone

+98 13 1321 0343

Fax

Email

smkrimaz@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan university of medical sciences

Full name of responsible person

Dr. siamak Rimaz

Position

Assintant professor

Other areas of specialty/work

Street address

Namjoo Avenue, Deputy department

City

rasht

Postal code

Phone

+98 13 3366 3070

Fax

Email

smkrimaz@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan university of medical sciences

Full name of responsible person

Dr. siamak Rimaz

Position

assistant professor

Other areas of specialty/work

Street address

Namjoo Avenue, research centre, Velaiat hospital

City

rasht

Postal code

Phone

+98 13 3366 3070

Fax

Email

smkrimaz@yahoo.com

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