

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the efficacy of Patoprazole, Metoclopramide, and Ondansetron in management of gastrointestinal symptoms in Thyroid cancer patients treated with I-131

Protocol summary

Summary

Objectives: There are several therapeutic approaches in thyroid carcinoma. One of these treatments is Radioiodine therapy after total thyroidectomy. Because of high prevalence of gastrointestinal symptoms (50%) in patients treated with I-131 and lack of effective therapy for these symptoms, this study was designed. **Design:** This study is a single blind clinical trial. **Settings and conducts:** All patients eligible for radioiodine therapy (sample volume=85) will be divided into 4 groups randomly and each group will receive one of the drugs. **Participants:** **Inclusion criteria:** 1- Patients affected by differentiated thyroid carcinoma, 2- All patients for whom total thyroidectomy is done. **Exclusion criteria:** 1- Pregnant women, 2- Lactating women. **Intervention:** 1- Metoclopramide Tab 10 mg 2 times daily 2- Pantoprazole Tab 20 mg 2 times daily 3- Ondansetron Tab 8 mg 2 times daily 4- Placebo (Starch Tab) 8 mg 2 times daily **Main outcome measure:** After administration of I-131, during 3 days of staying in hospital the incidence and severity of nausea and the incidence of vomiting will be recorded and at the end of the study the effect of each drug in comparison to placebo in controlling the nausea and vomiting will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061713705N1**
Registration date: **2013-08-11, 1392/05/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-11, 1392/05/20

Registrant information

Name

Marjan Mirzababae

Name of organization / entity

Taleqhani hospital/ Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-04-08, 1391/01/20

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Patoprazole, Metoclopramide, and Ondansetron in management of gastrointestinal symptoms in Thyroid cancer patients treated with I-131

Public title

Comparison of the efficacy of 3 drugs in prevention of side effects of radioiodine therapy in thyroid cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- All the patients affected by differentiated thyroid carcinoma. 2- All the patients for whom total thyroidectomy is done. Exclusion criteria: 1- Pregnant women 2- Lactating women

Age

From **15 years** old to **78 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **85**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University Of Medical Sciences

Street address

Aarabi street, Yaman street, Velanjak street

City

Tehran

Postal code

1985717443

Approval date

2012-10-28, 1391/08/07

Ethics committee reference number

124

Health conditions studied

1

Description of health condition studied

Thyroid carcinoma

ICD-10 code

C73

ICD-10 code description

Malignant neoplasm of thyroid gland

Primary outcomes

1

Description

Nausea

Timepoint

Daily for 3 days

Method of measurement

Check list(Mild, Moderate, and severe)

2

Description

Vomiting

Timepoint

Daily for 3 days

Method of measurement

check list (has, or has not)

Secondary outcomes

empty

Intervention groups

1

Description

First group: Metoclopramide, 10 mg, oral, 2 times daily, for 3 days

Category

Treatment - Drugs

2

Description

second group: Pantoprazole, 20 mg, oral, 2 times daily, for 3 days

Category

Treatment - Drugs

3

Description

Third group; Ondansetron, 8 mg, oral, 2 times daily, for 3 days

Category

Treatment - Drugs

4

Description

Forth group: Placebo(Starch Tablet), 8 mg, oral, 2 times daily, for 3 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Taleghani Hospital

Full name of responsible person

Dr. Marjan Mirzababae

Street address

Aarabi street, Yaman street, Velanjak street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Dr. Mohammad Rahmati Roodsari

Street address

Aarabi street, Yaman street, Velanjak street

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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

Vice chancellor for research, Shahid Beheshti University Of Medical Sciences

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

Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Dr. Marjan Mirzababae

Position

Nuclear Medicine Resident

Other areas of specialty/work

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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