

# 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)

##### Phone

+98 21 2292 2992

##### Email address

m.mirzababae@yahoo.com

#### 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*