

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluation of zinthoma efficacy in prevention of antiretrovirals nausea and vomiting in HIV positive patients

#### Protocol summary

##### Summary

In this study effect of zinthoma in prevention of antiretroviral-induced nausea and vomiting will be evaluated. HIV positive patients who are candidate for antiretroviral therapy and without history of gastrointestinal diseases, allergy to zinthoma or using of other drugs that can induce nausea and vomiting will be recruited. In this clinical trial 80 HIV positive patients will be simply randomized to drug (zinthoma 500 mg, 30 minute before each dose of antiretroviral every 12 h) or placebo (500 mg, 30 minute before each dose of antiretroviral every 12 h) for 14 days. Occurrence of nausea and its severity and also number of vomiting episodes will be evaluated daily by investigator. Visual analogue scale will be used for evaluation of severity of patients' nausea. Effects of zinthoma in prevention of antiretroviral induced nausea and vomiting will be assessed by comparing of numbers and severity of nausea and vomiting episodes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201305283449N12**

Registration date: **2013-06-17, 1392/03/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-06-17, 1392/03/27

##### Registrant information

##### Name

Hossein Khalili

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4715

##### Email address

khalilih@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Grant of Tehran University of Medical Sciences

##### Expected recruitment start date

2011-02-01, 1389/11/12

##### Expected recruitment end date

2013-08-01, 1392/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of zinthoma efficacy in prevention of antiretrovirals nausea and vomiting in HIV positive patients

##### Public title

Zinthoma, Antiretroviral and Nausea and Vomiting

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: HIV positive patients who are candidate for Antiretroviral therapy and who signe study consent form. Exclusion criteria: History of zinthoma or othera herbal products hypersensitivity

##### Age

From **16 years** old to **65 years** old

##### Gender

Both

## Phase

4

## Groups that have been masked

No information

## Sample size

Target sample size: 80

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Ghods Ave, Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2010-08-26, 1389/06/04

#### Ethics committee reference number

89-03-33-11312

## Health conditions studied

### 1

#### Description of health condition studied

HIV/AIDS

#### ICD-10 code

B20-B24

#### ICD-10 code description

Human immunodeficiency virus [HIV] disease

## Primary outcomes

### 1

#### Description

Frequency of Nausea and Vomiting

#### Timepoint

During 2 weeks of starting antiretroviral

#### Method of measurement

Visual analogue scale

## Secondary outcomes

### 1

#### Description

Severity of nausea

#### Timepoint

Dring 2 weeks of starting antiretroviral

#### Method of measurement

Visual analogue scale

## Intervention groups

### 1

#### Description

Intervention (Drug): Zinthoma 2 Cap (500 mg)30 minutes before each dose of antiretroviral twice daily for 14 days

#### Category

Treatment - Drugs

### 2

#### Description

Control: Placebo 2 Cap ( 500 mg) 30 minutes before each dose of antiretroviral twice daily for 14 days

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Hossein Khalili

##### Street address

keshavarz BLV.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Fatemeh Saeedi

##### Street address

Tehran University of Medical Sciences, Ghods Ave, keshavarz Blv, Tehran, Iran

##### 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

**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**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khalili

**Position**

Pharm D

**Other areas of specialty/work**

**Street address**

Tehran University of Medical Sciences, Enghelab Ave,  
Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 6695 4709

**Fax**

**Email**

khalilih@tums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein khalili

**Position**

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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*