

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

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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