

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The role of piperine on the salivary concentration of caffeine as a main CYP1A2 probe

Protocol summary

Summary

Piperine, the main alkaloid of black pepper, involves to activity of liver enzymes, including CYP1A2. Caffeine is primarily metabolized by this enzyme, so that the Saliva concentration of the drug is a criterion of CYP1A2 activity. Healthy volunteers are recruited. The main inclusion criteria are general health status, age between 18 to 35, no taking of enzyme inhibitor or inducer drugs and food enriched of black pepper as additive. And exclusion criteria are each chronic or metabolic disorders, and taking enzyme inhibitors and inducers. Crossover study to be carried out with one month period as wash out time. Healthy volunteer regardless gender, are randomly divided into two control and piperine receiving groups (n=20). The subject will receive placebo or piperine (1 capsule daily for 3 days before Caffeine) and Caffeine (10 mg as an oral single dose on fourth day of the study. Total period of the study is 4 days. Blood samples will be taken at 0, 0.5, 2.5 and 5 hr after Caffeine administration. The Caffeine Saliva concentration will be assayed using HPLC method. Pharmacokinetic parameters such as Saliva concentrations, clearance, half-life and volume of distribution of Caffeine in the placebo will be compared with the findings of piperine group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209239271N3**
Registration date: **2012-10-05, 1391/07/14**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-10-05, 1391/07/14

Registrant information

Name

Ali Akbar Moghadamnia

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1222 9591

Email address

a.moghadamnia@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Affairs of Babol University of Medical Sciences

Expected recruitment start date

2012-10-21, 1391/07/30

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of piperine on the salivary concentration of caffeine as a main CYP1A2 probe

Public title

Piperine effect on caffeine salivary concentration

Purpose

Basic science

Inclusion/Exclusion criteria

After providing adequate information to the subjects, eligible healthy volunteer will be enrolled in the study. Inclusion criteria: be healthy; normal diet; not receiving microsomal enzyme inhibitor or inducer agents for at least 7 days before the study; not using black pepper for

at least 7 days before the study; not using caffeine containing product 48 h before the study. Exclusion criteria: age below 18 and above 35; smoking; pregnancy; metabolic disorders; high pepper diet, receiving enzyme inhibitors or inducers.

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Babol University of Medical Sciences

Street address

University Sq, Ganje Afrooze Ave.

City

Babol

Postal code

4717641367

Approval date

2011-12-31, 1390/10/10

Ethics committee reference number

5337/30/پ

Health conditions studied**1****Description of health condition studied**

Pharmacokinetics

ICD-10 code

Z00

ICD-10 code description

General examination and investigation of persons without complaint and reported diagnosis

Primary outcomes**1****Description**

Caffeine Saliva Concentration

Timepoint

Only once in fourth day of the study 0, 0.5, 2.5 and 5 h after taking Caffeine

Method of measurement

Using HPLC method (reverse phase; Water 25, Methanol 75, flow rate 0.8 ml/min, maximum wave length 242 nm)

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: administration placebo one capsule daily for three days before Caffeine (50 mg oral single dose).

Category

Other

2**Description**

Piperine group: administration piperine (15 mg) one capsule daily for three days before Caffeine (50 mg oral single dose).

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Moghadamnia

Street address

Department of Pharmacology, Faculty of Medicine, Babol University of Medical Sciences

City

Babol

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Ganje Afrooze Ave. University SQ.

City
Babol

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Dr. Ali Akbar Moghadamnia

Position
PhD

Other areas of specialty/work

Street address
Department of Pharmacology, Faculty of Medicine

City
Babol

Postal code
4717641367

Phone
+98 11 1219 2033

Fax

Email
moghadamnia@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Ali Akbar Moghadamnia

Position
PharmD, PhD

Other areas of specialty/work

Street address
Department of Pharmacology, Faculty of Medicine,
Babol University of Medical Sciences

City
Babol

Postal code
4717641367

Phone
+98 11 1219 2033

Fax

Email
a.moghadamnia@mybabol.ac.irmoghadamnia@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Ali Akbar Moghadamnia

Position
PharmD, PhD

Other areas of specialty/work

Street address
Department of Pharmacology, Faculty of Medicine,
Babol University of Medical Sciences, Ganje Afrooze
Ave,

City
Babol

Postal code
4717641367

Phone
+98 11 1219 2033

Fax

Email
moghadamnia@gmail.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