Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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Name of organization / entity

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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 scienece

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.

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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

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

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Sponsors / Funding sources

1

Sponsor

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Babol University of Medical Sciences

Full name of responsible person
Dr. Ali Bijani

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Ganje Afrooze Ave. University SQ.

City
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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
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

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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