

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### comprasion of antiplatelet activity of garlic tablets with cardioprotective dose of aspirin (80mg/day)in healthy volunteers

#### Protocol summary

##### Summary

Objective: Some of the adverse effects of aspirin including peptic ulcers, gastrointestinal bleeding and aspirin resistance completed researchers to look for search for a suitable alternative with fewer adverse effects. The aim of this study was to determine the mechanism of antiplatelet effects of garlic and then, in a clinical trial, obtain the effective dose of antiplatelet effects of garlic. Method: This Randomized controlled clinical trial (RCT) was conducted on 62 healthy volunteers with age range of 20 to 50 years. Platelet aggregation induced by 4 known agonists acting in aggregation pathway including ADP(20 $\mu$  mol/l) , epinephrine( EPN)( 20 $\mu$  mol/ l ), collagen(0.19 mg/ ml ) and arachidonic acid (AA)( 0.5mg/ ml ) was measured by Light Transmittance Aggregometry (LTA; HELENA PACKS -4). All volunteers used 80 mg aspirin per day for 1 week and at the end of this time, platelet aggregation (PA) was measured by the mentioned agonists. To find an effective dose of garlic, volunteers were divided into 3 groups and each received 1, or 2 or 3 garlic tablets a day for 1 month, randomly. After one month PA was examined for all groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012073110453N1**

Registration date: **2014-09-26, 1393/07/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-09-26, 1393/07/04

##### Registrant information

##### Name

Mojtaba Shafiekhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3242 4255

##### Email address

mshafikhan@sums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Pharmaceutical Science Research Center(PSRC) OF Shiraz University Of Medical Sciences

##### Expected recruitment start date

2014-08-24, 1393/06/02

##### Expected recruitment end date

2014-09-01, 1393/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comprasion of antiplatelet activity of garlic tablets with cardioprotective dose of aspirin (80mg/day)in healthy volunteers

##### Public title

antiplatelet effects of garlic

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Exclusion criteria applied to individuals who had cardiovascular disease, been using aspirin, clopidogrel and nonsteroidal anti inflammatory drugs ( NSAIDS) in the last 2 weeks ago , thrombocytopenia(platelet<100 × 10<sup>3</sup> platelets /mm<sup>3</sup> ),

anemia(hemoglobin<10g/dl),abnormal lipid profile[total cholesterol  $\geq$  200 mg/dl , LDL-C  $\geq$ 100mg/dl , TG  $\geq$  200 mg/dl HDL $\leq$  45 mg/dl(male) and  $\leq$  55 mg/dl(female) ], Diabetes mellitus (FBS  $\geq$  126 mg/ dl confirmed by repeating the test), and renal failure[Serum creatinine  $\geq$  2mg/dl (female) and Serum creatinine $\geq$ 2.5 mg/dl (male)] inclusion criteria : 62 healthy individuals(non diabetic : normal lipid profile : without any cardiovascular disease and coagulation disorders :non used aspirin, clopidogrel and nonsteroidal anti inflammatory drugs ( NSAIDS) in the last 2 weeks ago aged 20-50 years old were enrolled in this clinical trial.

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 62

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shiraz University of Medical Sciences

**Street address**

Zand blvd

**City**

Shiraz

**Postal code****Approval date**

2010-08-20, 1389/05/29

**Ethics committee reference number**

ct-p-91-4598

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

agents affecting blood constituents

**ICD-10 code**

Y44.9

**ICD-10 code description**

Other and unspecified agents affecting blood constituents

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

platelet aggregation

**Timepoint**

3 months

**Method of measurement**

Light transmission aggregometer

**Secondary outcomes**

empty

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

garlic 1250mg one tablet a day for 30 days

**Category**

Treatment - Drugs

**2****Description**

garlic(1250mg) 2 tablets a day for 30 days

**Category**

Treatment - Drugs

**3****Description**

3 tablets(1250 mg) garlic a day for 30 days

**Category**

Treatment - Drugs

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

Shahid Dastgheib Hospital

**Full name of responsible person**

Mojtaba Shafikhani

**Street address**

Hafeziye Blvd

**City**

Shiraz

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Pharmaceutical Siences Reseaserch

**Full name of responsible person**

Dr. Yunes Ghasemi

**Street address**

Zand blvd

**City**

Shiraz

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

Yes

**Title of funding source**

Pharmaceutical Siences Reseaserch

**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**

Shiraz University Of Medical Sciences

**Full name of responsible person**

Mojtaba Shafikhani

**Position**

student

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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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*