

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of low dose aspirin on platelet inhibition in patients with rheumatoid arthritis

#### Protocol summary

##### Summary

A total of 45 patients with rheumatoid arthritis who have been diagnosed with EULAR 2010 ACR criteria and 6 months of their illness are enrolled in the study. Patients are examined at the beginning of the study and a questionnaire containing disease information is available. Height, weight, abdominal circumference, number of sensitive and swollen joints, and duration of disease and type of medication are recorded. The disease activity is based on DAS28 and SDAI and Before starting the administration of the patients, 5 ml of blood was taken after 8-10 hours of fasting and transferred to the glass tubes and after the creation of a clot and centrifuge with about 3000 RPM for 15 minutes, the serum would be isolated. Samples Serum will be transferred to the tubes for TBX2 measurement and will be transferred to the freezer -70 degrees Then 80 mg of spray will be administered to the study group, which lasts for one week, and after the last administration, the sampling will be repeated under completely identical conditions.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201707293812N6**

Registration date: **2017-08-08, 1396/05/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-08, 1396/05/17

##### Registrant information

##### Name

Amir Ghorbanihaghjo

##### Name of organization / entity

Biotechnology Research Center, Tabriz University of Medical Sciences, Tabriz 51664, Iran.

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 3234

##### Email address

ghorbani@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Connective Tissue Disease Research Center. Tabriz University of Medical sciences

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2018-02-19, 1396/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of low dose aspirin on platelet inhibition in patients with rheumatoid arthritis

##### Public title

The effect of low dose aspirin on platelet inhibition in patients with rheumatoid arthritis

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with rheumatoid arthritis who have been diagnosed with EULAR 2010 ACR criteria and have been ill for 6 months Exclusion criteria: Includes recent use of aspirin and anti-coagulant drugs, history of aspirin allergy, renal failure (creatinine above 8.1 mg / dL), thrombotic cytopenia, pregnancy, gastric ulcer and

gastrointestinal bleeding. Patients with maternal and metabolic disorders are also among the exclusion criteria.

**Age**

No age limit

**Gender**

Both

**Phase**

1

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

N/A

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

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

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

empty

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

Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences

**City**

Tabriz

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

2010-09-23, 1389/07/01

**Ethics committee reference number**

IR.TBZMED.REC.1395.638

**2****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences- Tabriz- Iran

**City**

Tabriz

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

2010-08-20, 1389/05/29

**Ethics committee reference number**

IR.TBZMED.REC.1395.638

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

Rheumatoid arthritis

**ICD-10 code**

M06.9

**ICD-10 code description**

Rheumatoid arthritis, unspecified

**2****Description of health condition studied**

Rheumatoid arthritis

**ICD-10 code**

M06.9

**ICD-10 code description**

Rheumatoid arthritis, unspecified

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

platelet aggregation

**Timepoint**

One week

**Method of measurement**

Elisa

**Secondary outcomes****1****Description**

TXA2

**Timepoint**

one weak

**Method of measurement**

Elisa

**2****Description**

TX-A2

**Timepoint**

One week

**Method of measurement**

Elisa

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

Prescribing 80 mg of aspirin on the patient's group and taking the drug for one week. After the last dose and re sampling, blood samples will be used to measure serum TX levels

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Emam reza Hospital - Tabriz University of Medical sciences

**Full name of responsible person**

Dr. Hajjalilo

**Street address****City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Connective Tissue research Center- Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Khabazi

**Street address**

Connective Tissue research Center- Tabriz University of Medical Sciences

**City**

Tabriz

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

Yes

**Title of funding source**

Connective Tissue research Center- Tabriz University of Medical Sciences

**Proportion provided by this source****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*

2

### Sponsor

**Name of organization / entity**

abriz University of Medical Sciences, Tabriz, Iran

**Full name of responsible person**

Dr.Khabbazi

**Street address**

Connective Tissue Diseases Research Center, Tabriz University of Medical Sciences, Tabriz, Iran.

**City**

Tabriz

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

Yes

**Title of funding source**

abriz University of Medical Sciences, Tabriz, Iran

**Proportion provided by this source****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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Amir ghorbanihaghjo

**Position**

Phd

**Other areas of specialty/work****Street address**

Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code****Phone**

+98 41 3336 4666

**Fax****Email**

ghorbaniamir@hotmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz university of Medical Sciences

**Full name of responsible person**

Mahrzad Hajjalilo

**Position**

rheumatologist

**Other areas of specialty/work****Street address**

Tabriz university of Medical Sciences

**City**

Tabriz

**Postal code**

Iran

**Phone**

+33 364666

**Fax****Email**

hajjalilo@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Amir Ghorbanihaghjo

**Position**

PhD

**Other areas of specialty/work****Street address**

Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code****Phone**

+98 41133364666

**Fax****Email**

## 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*