

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the Effect of Nervoxin commercial herbal medicine on liver clearance of 99mTc-Sestamibi in human's myocardial perfusion scan

Protocol summary

Study aim

1. Determining the effect of Nervoxin on Liver clearance of 99mTc-MIBI in Human's Myocardial Perfusion Scan
2. Determination the heart and liver activity in both control and intervention groups and comparing them with each other
3. Determining the heart to liver activity ratio in both control and intervention groups and comparing them with each other

Design

A clinical trial with control and intervention groups on 60 patients

Settings and conduct

60 patients are selected from the patients referred to nuclear medicine department of Fatemeh Zahra hospital and are classified into two groups of control and intervention. 30 patients are daily received 900mg of Nervoxin for 5 days. 24 hours after the last dose, the Myocardial perfusion (MPI) scan will be performed in accordance with the standard protocols. Finally, all data obtained from human heart myocardial perfusion scans will be processed at the center and will be sorted by professors and quantified as statistical data.

Participants/Inclusion and exclusion criteria

Patients without previous history of cholecystectomy; liver- biliary disease; hepatic and renal failure, coagulopathy; history of myocardial infarction and heart valve disease and heart failure and patient who don't take medicine such as digoxin, warfarin and theophyllin are enrolled in the study.

Intervention groups

Intervention group: 30 patients are received nervoxin 5 days before scanning, which is discontinued for 24h before Myocardial perfusion (MPI) scan. Control group: 30 people with no additional intervention prior to Myocardial perfusion (MPI) scan.

Main outcome variables

- 1- Increased liver clearance of 99mTc-sestamibi
- 2- Increased hear to liver radioactivity ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200803048277N1**

Registration date: **2020-10-14, 1399/07/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-14, 1399/07/23**

Update count: **0**

Registration date

2020-10-14, 1399/07/23

Registrant information

Name

Zohreh Noaparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3463 2525

Email address

z_noaparast@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Nervoxin commercial herbal medicine on liver clearance of 99mTc-Sestamibi in human's myocardial perfusion scan

Public title

effect of Nervoxin on hepatic clearance of 99mTc-Sestamibi

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients except patients taking drugs that interact with nervoxin, such as digoxin, warfarin, theophylline, etc. All patients except those with known hepatic and renal failure, patients with coagulation problems and heart disease.

Exclusion criteria:

Patients taking drugs that interact with nervoxin, such as digoxin, warfarin, theophylline, etc. People with known hepatic and renal failure, patients with coagulation problems and heart patients

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not 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**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Valie-Asr Boulevard, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

4715733971

Approval date

2020-07-14, 1399/04/24

Ethics committee reference number

IR.MAZUMS..REC.1399.7985

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

Myocardial perfusion

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

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

99mTc-MIBI accumulation in liver

Timepoint

24 hours after receiving the last dose of Nervoxin

Method of measurement

Imaging with gamma camera

2**Description**

Heart to liver activity ratio

Timepoint

24 hours after receiving the last dose of Nervoxin

Method of measurement

Imaging with gamma camera

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

Difference Score in liver clearance of 99mTc-MIBI between control and intervention groups

Timepoint

After myocardial perfusion scan

Method of measurement

Imaging with gamma camera

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

Intervention group: 30 patients received Nervoxin drug

Category

Diagnosis

2

Description

Control group: 30 patients who don't receive any intervention

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuclear Medicine Department of Fateme Zahra hospital

Full name of responsible person

Zohreh Noaparast

Street address

Faculty of pharmacy, Payambar Azam academic complex, 18 km of Khazar Abad Ave, Sari

City

Sari

Province

Mazandaran

Postal code

4715733971

Phone

+98 11 3304 4000

Email

z_noaparast@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Mazandaran University of Medical Sciences, Moalem Sq., Sari., Mazandaran., Iran

City

Sari

Province

Mazandaran

Postal code

4715733971

Phone

+98 11 3304 4000

Email

publicrel@mazums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice Chancellor for Research and Technology,

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zohreh Noaparast

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of pharmacy, Payambar Azam academic complex, 18 km of Khazar Abad Ave, Sari

City

Sari

Province

Mazandaran

Postal code

4715733971

Phone

+98 11 3304 4000

Email

z_noaparast@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zohreh Noaparast

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of pharmacy, Payambar Azam academic complex, 18 km of Khazar Abad Ave, Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3463 2525

Fax

+98 11 3354 3084

Email

z_noaparast@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zohreh Noaparast

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of pharmacy, Payambar Azam academic complex, 18 km of Khazar Abad Ave, Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3463 2525

Fax

+98 11 3354 3084

Email

z_noaparast@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

At the end of the study, details of the study method, statistical analysis and results related to cardiac perfusion scans in patients will be published in detail as a research article.

When the data will become available and for how long

Access to the data file and details of the results is possible after the publication of the article

To whom data/document is available

Only reputable academic institutions, especially medicinal researcher will be allowed to receive data

Under which criteria data/document could be used

Researchers who study on myocardial perfusion scan

From where data/document is obtainable

Applicants can receive the information via the mentioned email address Dr. Zohreh Noaparast:

z_noaparast@yahoo.com, z.noparast@mazums.ac.ir Dr.

Seyed Mohammad Abedi: mabedi167@yahoo.com

What processes are involved for a request to access data/document

Email to the applicant - request from University Research Assistant - If their opinion is positive, information will be provided to the applicant

Comments