

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The Effect of aerobic exercise on hepatic enzymes and tissue after the intratracheal instillation of iron oxide nanoparticles in wistar rats

#### Protocol summary

##### Summary

Background & objective : In this study we investigated the effect of concurrent aerobic exercise and inhalation iron oxide nanoparticles on hepatic enzymes; ALT, AST, ALP and histological hepatic appearance. Design: This study was an experimental study with post-test and control group. Inclusion criteria: public health; physical ability; normal limbs. Exclusion criteria: physical disability. 48 wistar rats with a mean weight of 250gr were randomly divided into six equal groups including of the experimental 1(aerobic, exercise), experimental 2(nanoparticle, anesthesia), experimental 3(aerobic exercise, nanoparticles & anesthesia), placebo 4(distillated water, anesthesia), placebo 5(aerobic exercise, anesthetists), and control group. In group 2 and 3, 40mg/ kgbw iron oxide nanoparticles injected every other day for a period of 14 days with lung induction method. Groups 4, 1, and 3 had to run on treadmill everyday for 30 minutes with the intensity of 35% to 40%VO<sub>2</sub>max. Intervention: intratracheal instillation of iron oxide nanoparticles, aerobic exercise. Main Outcome Measures (variables): 24 hours after last exercise session blood samples were analyzed to measure the amount of hepatic enzymes(ALT, AST, ALP). For histopathology examination the tissue sections were studied by light microscope.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014021816624N1**

Registration date: **2014-03-25, 1393/01/05**

Registration timing: **prospective**

Last update:

Update count: **0**

**Registration date**

2014-03-25, 1393/01/05

##### Registrant information

###### Name

Azadeh Vasili

###### Name of organization / entity

Khorasgan(Isfahan)Branch, Islamic Azad University

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Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2014-04-04, 1393/01/15

##### Expected recruitment end date

2014-04-19, 1393/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of aerobic exercise on hepatic enzymes and tissue after the intratracheal instillation of iron oxide nanoparticles in wistar rats

##### Public title

The Effect of aerobic exercise on hepatotoxicity induced by intratracheal instillation of iron oxide nanoparticles in wistar rats

##### Purpose

Basic science

##### Inclusion/Exclusion criteria

Inclusion criteria: public health; physical ability; normal limbs  
Exclusion criteria: physical disability.

## Age

From **1 year** old to **1 year** old

## Gender

Male

## Phase

1

## Groups that have been masked

No information

## Sample size

Target sample size: **48**

## 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

Regional Committee for Medical Research Ethics of the vice chancellor for research, Isfahan University

##### Street address

Bldg no4, Isfahan medical university, Hezarjib st, Isfahan

##### City

Isfahan

##### Postal code

81745-319

#### Approval date

2014-02-10, 1392/11/21

#### Ethics committee reference number

492044

## Health conditions studied

### 1

#### Description of health condition studied

hepatotoxicity

#### ICD-10 code

K71.1

#### ICD-10 code description

Hepatic failure (acute)(chronic) due to drugs

## Primary outcomes

### 1

#### Description

ALT

#### Timepoint

14 days after the intervention

#### Method of measurement

Enzyme units per liter

### 2

#### Description

AST

#### Timepoint

14 days after the intervention

#### Method of measurement

Enzyme units per liter

### 3

#### Description

ALP

#### Timepoint

14 days after the intervention

#### Method of measurement

Enzyme units per liter

## Secondary outcomes

### 1

#### Description

Hepatic tissue sections

#### Timepoint

14 days after the intervention

#### Method of measurement

Observed slides hepatic tissues sections

## Intervention groups

### 1

#### Description

Experimental 3(aerobic exercise, nanoparticles & anesthesia): in this group, at first rats ran on a treadmill then anesthetized and iron oxide nanoparticles were injected into their trachea. Aerobic exercise: male wistar rats were trained to do low-intensity aerobic exercise. With an intensity of approximately 35% to 40% VO<sub>2</sub>max, they ran on a motor-driven treadmill designed for rats for 30 minutes in each day within 2 weeks. The sequence of this exercise were as follows: exercise in 5 minutes at a speed of 6 m/min, exercise in 5 minutes at a speed of 9 m/min and exercise in 20 minutes at a speed of 12 m/min with a running intensity of 35% to 40% VO<sub>2</sub>max. Intratracheal instillation of Iron oxide nanoparticles: as concerns intratracheal instillation for every injection, a 0.1ml dose of 100mg/ml distilled water and IONPs suspension solution has been injected into the rat's trachea. The required amount of dose was

40mg/kgbw. Administration repeated 7 times every other day in 14 day. At any time of the injection, the rats were anesthetized by inhalation of ether and weighed.

**Category**

Treatment - Drugs

**2**

**Description**

Experimental group (1)(aerobic exercise): in this group male wistar rats were trained to do low-intensity aerobic exercise. With an intensity of approximately 35% to 40% VO2max, they ran on a motor-driven treadmill designed for rats for 30 minutes in each day within 2 weeks. The sequence of this exercise were as follows: exercise in 5 minutes at a speed of 6 m/min, exercise in 5 minutes at a speed of 9 m/min and exercise in 20 minutes at a speed of 12 m/min with a running intensity of 35% to 40% VO2max.

**Category**

Other

**3**

**Description**

Experimental 2(nanoparticle, anesthesia): as concerns intratracheal instillation for every injection, a 0.1ml dose of 100mg/ml distilled water and IONPs suspension solution has been injected into the rat's thetrachea. The required amount of dose was 40mg/kgbw. Administration repeated 7 times every other day in 14 day. At any time of the injection, the rats were anesthetized by inhalation of ether and weighed.

**Category**

Diagnosis

**4**

**Description**

Control group: this group did not receive any intervention and were weighed every day.

**Category**

Diagnosis

**5**

**Description**

Placebo 4(distillated water, anesthesia): as concerns intratracheal instillation for every injection, a 0.1ml distilled water has been injected into the rat's thetrachea. Administration repeated 7 times every other day in 14 day. At any time of the injection, the rats were anesthetized by inhalation of ether and weighed.

**Category**

Treatment - Drugs

**6**

**Description**

Placebo 5(aerobic exercise, anesthetists): at first rats ran on a treadmill then anesthetized and weighed. Rats were trained to do low-intensity aerobic exercise. With an intensity of approximately 35% to 40% VO2max, they

ran on a motor-driven treadmill designed for rats for 30 minutes in each day within 2 weeks. The sequence of this exercise were as follows: exercise in 5 minutes at a speed of 6 m/min, exercise in 5 minutes at a speed of 9 m/min and exercise in 20 minutes at a speed of 12 m/min with a running intensity of 35% to 40% VO2max.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Veterinary clinic of doctor Shahriyar Adibi

**Full name of responsible person**

Doctor Shahriyar Adibi(DVM)

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NO.12, three-way airport, East J St, Isfahan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

vice chancellor for research, Islamic Azad University  
Isfahan(Khorasgan)Branch

**Full name of responsible person**

Doctor Payam Najafi

**Street address**

University Blvd, Arghavanyeh, Khorasgan, Isfahan

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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**

vice chancellor for research, Islamic Azad University  
Isfahan(Khorasgan)Branch

**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**

Islamic Azad University Isfahan(Khorasgan) Branch

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Doctor Gholamreza Sharifi

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## Person responsible for scientific 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*