

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%VO₂max. 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

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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

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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% 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. 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	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
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	Recruitment centers 1 Recruitment center Name of recruitment center Veterinary clinic of doctor Shahriyar Adibi Full name of responsible person Doctor Shahriyar Adibi(DVM) Street address NO.12, three-way airport, East J St, Isfahan City Isfahan
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	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 City Isfahan
4 Description Control group: this group did not receive any intervention and were weighed every day. Category Diagnosis	Grant name Grant code / Reference number Is the source of funding the same sponsor organization/entity? Yes
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	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
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	Person responsible for general inquiries Contact Name of organization / entity Islamic Azad University Isfahan(Khorasgan) Branch

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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