

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The Effect of Selected Mod of Physical Activity During Shift Work on Cardiovascular Biomarkers in Sarirplast Industrial Group Workers

Protocol summary

Study aim

Determination of the effect of selected mod of physical activity during shift work on cardiovascular biomarkers in Sarirplast Industrial Group Workers

Design

The Research will be conducted with two experimental and control groups. After reviewing the data of the self-report questionnaires by shift workers, The 30 persons with the entry criteria for the research will be selected as sample in a targeted sampling. Then subjects will be assigned to one of the two groups; intervention (n = 15) and control (n = 15), randomly.

Settings and conduct

The site of the present research will be Dezfoul Industrial Group that consists of five affiliated companies. The statistical population of the survey will be all the shift workers of this industrial group. Research will be a quasi-experimental research with pre-test and post-test design with two experimental and control groups. Blinding will not be done in this research.

Participants/Inclusion and exclusion criteria

men shift workers with at least 5 years shift work no smoking Lack of chronic cardiovascular disease, uncontrolled blood pressure and respiratory diseases Lack of diseases and musculoskeletal problems Lack of diabetes, infectious and inflammatory diseases Lack of history of recurrent hypoglycemia or during exercise Not having regular exercise in the last six months

Intervention groups

The intervention will be aerobic physical activity (running), which will be performed three days a week with a rest day between the training sessions and for 8 weeks. Only the experimental group will perform the intervention.

Main outcome variables

Body Weight, Body Mass Index, Wrist Hip Ratio, Body Fat Percentage, Visceral Fat, Systolic and Diastolic Blood Pressure, Blood Lipids and Lipoprotein, Rest Heart Rate, Cardiac Troponin I, C-Reactive Protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190702044080N1**

Registration date: **2019-08-30, 1398/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-30, 1398/06/08**

Update count: **0**

Registration date

2019-08-30, 1398/06/08

Registrant information

Name

Aboutaleb Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4255 5298

Email address

taleb bagheri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Selected Mod of Physical Activity During Shift Work on Cardiovascular Biomarkers in Sarirplast Industrial Group Workers

Public title

The Effect of Selected Mod of Physical Activity During Shift Work on Cardiovascular Biomarkers in Sarirplast Industrial Group Workers

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

men shift workers aged 25 to 40 years at least 5 years of shift work history no smoking lack of chronic cardiovascular disease lack of uncontrolled blood pressure lack of respiratory diseases lack of severe skeletal and articular problems lack of diabetes lack of infectious and inflammatory diseases lack of history of recurrent hypoglycemia or during exercise Not having regular exercise in the last six months

Exclusion criteria:

infected with other infectious diseases

Age

From **25 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The volunteer candidates will be selected by targeted sampling. For shift workers, a random number will be assigned an identification number. So a range of 00 to 29 will be determined. Two equal groups (n = 15) will be formed. The samples will be divided into intervention and control groups using random numbers. The first number entered into the intervention group and the second to the control group; this process will continue to accommodate 15 individuals in each group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

empty

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

Ethics committee of Islamic Azad University- Science and Research Branch

Street address

Science and Research Branch, Hessarak Blvd, University Square, Shahid Sattari Highway

City

Tehran

Province

Tehran

Postal code

۱۴۷۷۸۹۳۸۵۵

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.IAU.SRB.REC.1398.007

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

Cardiovascular biomarkers

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

cardiac troponin I

Timepoint

Blood sampling 48 hours before the first training session (intervention) and 48 hours after the last training session (intervention)

Method of measurement

French Biosynex kit by ELISA method

2**Description**

High Sensitive-C-Reactive Protein

Timepoint

Blood sampling 48 hours before the first training session (intervention) and 48 hours after the last training session (intervention)

Method of measurement

England Omega Diagnostics LTD kit by ELISA method

3**Description**

Blood lipids and lipoproteins

Timepoint

Blood sampling 48 hours before the first training session (intervention) and 48 hours after the last training session

(intervention)

Method of measurement

by Spectrophotometer device

4

Description

Systolic and diastolic blood pressure

Timepoint

48 hours before the first training session (intervention) and 48 hours after the last training session (intervention)

Method of measurement

With Digital Blood Pressure (Norditalia BP-510, Italy) from the left wrist

5

Description

Anthropometric Indicators

Timepoint

48 hours before the first training session (intervention) and 48 hours after the last training session (intervention)

Method of measurement

height by Seca stadimeter; body weight, body mass Index, body fat percentage, and visceral by Omron impedance bio-electrical device; and The wrist hip ratio by non-elastic meter strip

6

Description

Rest Heart Rate

Timepoint

48 hours before the first training session (intervention) and 48 hours after the last training session (intervention)

Method of measurement

With Digital Norditalia (BP-510, Italy)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: According to the World Health Organization's recommendation for weight adjustment and risk reduction of cardiovascular disease, physical activity with moderate intensity is determined for intervention group. Intervention is conducted 3 days a week with a day rest between sessions and for 8 weeks at 17-19 pm. Each session consists of 10 minutes of warm-up (running and stretching), 30 minutes of running, and 5 to 7 minutes of cool-down (running and stretching) with the examiner's supervision. To observe the principle of over-load, the physical activity of the intervention group starts at 50% of the Target Heart Rate and will reach 70% in the final weeks. The activity is controlled by the beaconometer. So high-fatty foods (especially for shimmering) will be eliminated. This will be controlled by the supervision.

Category

Prevention

2

Description

Control group: No exercise intervention will be received by the researcher; only the pre-blood donation recommendations will be received. The control group will be required to inform the researcher in case of regular exercise and use of medicinal and non-prescriptive supplements, in order to eliminate them if necessary. So high-fatty foods (especially for shimmering) will be eliminated. This will be controlled by the supervision.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarirplast Industrial Group Workers

Full name of responsible person

Mohsen Ghasaban Nezhad

Street address

4th st, Industrial Town No. 1

City

Dezful

Province

Khouzestan

Postal code

1234567899

Phone

+98 61 4242 9897

Email

mohsen_adiban@yahoo.com

Web page address

<http://sarirplast.com/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Heidari Moghadam

Street address

Dezful Islamic Azad University, University blvd, Azadegan

City

Dezful

Province

Khouzestan

Postal code

6461645169

Phone

+98 61 4242 0601

Email

rvp@iaud.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Nader Shakeri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Islamic Azad University Science and Research Branch,
Hessarak blvd, University Square, Shahid Sattari
Highway

City

Tehran

Province

Tehran

Postal code

1669445564

Phone

+98 21 4486 5179

Email

nsprofsport@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nader Shakeri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Islamic Azad University Science and Research Branch,
Hessarak blvd, University Square, Shahid Sattari
Highway

City

Tehran

Province

Tehran

Postal code

1669445564

Phone

+98 21 4486 5179

Email

nsprofsport@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Aboutaleb Bagheri

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Sport Medicine

Street address

Islamic Azad University-Dezful Branch, University blvd

City

Dezful

Province

Khuzestan

Postal code

6461837894

Phone

+98 61 4255 5298

Email

talebbaagheri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available