

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effect of henna on pulse oximetry results in healthy and cardiopulmonary patients female.

#### Protocol summary

##### Summary

This research is a clinical trial. The purpose of this research is to determine the effect of henna on saturation pressure Oxygen (spo2), reading by pulse oximetry. Research population includes all healthy and cardio-respiratory patients' women with 20 - 60 years old with normal hemoglobin and normal body temperature that are eligible to study. Research settings are Intensive Care Units and Internal Medicine Ward and Dormitories of Tehran University of Medical Sciences. Samples consist of 40 healthy and young women, living in a Dormitory of Tehran University of Medical Sciences and 40 patients with cardiopulmonary disease. Sampling is convenience. Before intervention plasma sample will be collected from all of participants and body temperature will be measured by thermometer. Individuals will be participated in this study if their Hb is 12-15 gr/dl and body temperatures are between 36.8 -37.4°C. At first demographic data and disease information will be gathered, and then SPO2 will be measured in room temperature by calibrated pulse oximetry. If SPO2 is in the expected range (95-100% in healthy individual and up to 65%in patient group), red henna (Iranian henna) will be put on index finger's nail of non dominant hand and the other finger of the same hand will be considered as control. Then SPO2 will be measured by two calibrated pulse oximetry devices simultaneously. Finally, the value that will be displayed after ten minutes by two devices will be documented in an information form.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201209061599N20**

Registration date: **2012-12-29, 1391/10/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-12-29, 1391/10/09

##### Registrant information

###### Name

Mitra Zolfaghari

###### Name of organization / entity

Tehran University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6692 7171

###### Email address

zolfaghm@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2012-11-01, 1391/08/11

##### Expected recruitment end date

2013-03-01, 1391/12/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of henna on pulse oximetry results in healthy and cardiopulmonary patients female.

##### Public title

Effect of henna on pulse oximetry results

##### Purpose

Health service research

### **Inclusion/Exclusion criteria**

Inclusion criteria: 1. 20 - 60 years old 2. Hemoglobin(Hb) within 12-15 mg / dl 3 - normal body temperature (36 .8 -37 .4 °C) Exclusion criteria: 1- unconscious patients

### **Age**

From **20 years** old to **60 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **80**

### **Randomization (investigator's opinion)**

N/A

### **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 Tehran University of Medical Science

##### **Street address**

Ghods St. Tehran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2012-09-26, 1391/07/05

#### **Ethics committee reference number**

64984

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Pneumonia

#### **ICD-10 code**

J18

#### **ICD-10 code description**

Pneumonia, organism unspecified

### 2

#### **Description of health condition studied**

Bronchitis

#### **ICD-10 code**

J40

#### **ICD-10 code description**

Bronchitis, not specified as acute or chronic

### 3

#### **Description of health condition studied**

Pleural effusion

#### **ICD-10 code**

J90

#### **ICD-10 code description**

Pleural effusion, not elsewhere classified

### 4

#### **Description of health condition studied**

Hypertension

#### **ICD-10 code**

I11

#### **ICD-10 code description**

Hypertensive heart disease

### 5

#### **Description of health condition studied**

Acute myocardial infarction

#### **ICD-10 code**

I21

#### **ICD-10 code description**

Acute myocardial infarction

### 6

#### **Description of health condition studied**

Chronic ischaemic heart disease

#### **ICD-10 code**

I25

#### **ICD-10 code description**

Chronic ischaemic heart disease

## **Primary outcomes**

### 1

#### **Description**

Oxygen saturation percentage

#### **Timepoint**

one hour before intervention and one day after intervention

#### **Method of measurement**

pulse oximetry

## **Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

intervention 1: group 1: putting Iranian red henna with generic name " Lawsonia inermis "on nondominant hand of index finger nail in healthy participants that provide 1 gr henna dissolve in 10 CC water and put on finger nail for 2 hours.

#### Category

Other

### 2

#### Description

intervention 1: group 2: putting Iranian red henna with generic name " Lawsonia inermis "on nondominant hand of index finger nail in cardiac patient participants that provide 1 gr henna dissolve in 10 CC water and put on finger nail for 2 hours.

#### Category

Other

### 3

#### Description

1: group 3: putting Iranian red henna with generic name " Lawsonia inermis "on nondominant hand of index finger nail in respiratory patient participants that provide 1 gr henna dissolve in 10 CC water and put on finger nail for 2 hours.

#### Category

Other

### 4

#### Description

intervention 2 : group 1 absence henna and other barrier on middle finger of nondominant hand in healthy participant

#### Category

Other

### 5

#### Description

intervention 2 : group 2 absence henna and other barrier on middle finger of nondominant hand in cardiac patients

#### Category

Other

### 6

#### Description

intervention 2 : group3 absence henna and other barrier on middle finger of nondominant hand in respiratory patients

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Parisa Moradi Majd

##### Street address

Gharib St.

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Rasool Akram Hospital

##### Full name of responsible person

Parisa Moradi Majd

##### Street address

Satar Khan St.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

##### Full name of responsible person

Akbar Fotouhi

##### Street address

Vice Chancellor for Research, Tehran University of Medical Sciences. Ghods St. Keshavarz Bv.

##### City

Tehran

#### 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, Tehran University of Medical Sciences

#### 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Parisa Moradi Majd

**Position**

Student of Master of Sciences

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

No: 296 between Esfand and Eghbal, Esfahan St.

Golestan, Ahwaz

**City**

Ahwaz

**Postal code****Phone**

+98 61 1374 3228

**Fax****Email**

moradimajdparisa@yahoo.com

**Web page address****Email**

zolfaghm@tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parisa Moradi Majd

**Position**

Student of Master of Sciences

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

No: 296 between Esfand and Eghbal, Esfahan St.

Golestan, Ahwaz

**City**

Ahwaz

**Postal code****Phone**

+98 61 1374 3288

**Fax****Email**

moradimajdparisa@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mitra Zolfaghari

**Position**

PhD

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

Tohid Sq. Nosrat St. Nursing and Midwifery College

**City**

Tehran

**Postal code****Phone**

+98 21 6105 4402

**Fax**

## 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*