

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The Effect Of Acupuncture Before The Start Of Anesthesia On Hemodynamic Criteria Changes On Preeclamptic Pregnant Women Candidate For Cesarean Section.

Protocol summary

Summary

The Aim Of This Study Was To Evaluate The Efficacy Of Acupuncture Before The Start Of Anesthesia On Hemodynamic Criteria Changes On Preeclamptic Pregnant Women Undergoing Caesarean Section. It Is Randomized Clinical Trial And Triple Blinded Study. The Study Population Is Pregnant Women With Preeclampsia By A Gynecologist Diagnosed And Undergoing Caesarean Section At Valiasr Hospital Of Tehran. Inclusion Criteria Is The Diagnosis Of Preeclampsia. If Having Any Underlying Disease Or The Presence Of Contraindications For Acupuncture And Patient Unsatisfaction, The Person Will Be Excluded. The Study Population Is 98 Patients, Including 49 Cases And 49 Controls. At The Beginning Of Entering The Operating Room Initial Patient's Hemodynamic Will Be Assessed And Then Acupuncture Specialist Will Acupuncture. The Process Of Induction Of Anesthesia And Hemodynamic Changes At Different Times Are Measured And Entered In The Questionnaire. These Variables Include Systolic And Diastolic Blood Pressure , Arterial Saturation And Heart Rate Per Minute . In The Control Group , The Needles Are Improperly Applied And Then Hemodynamic Changes Compare With The Intervention Group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101924605N1**

Registration date: **2016-01-13, 1394/10/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-13, 1394/10/23

Registrant information

Name

seyyedeh golnaz sadeghian baboli

Name of organization / entity

tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 2227 8470

Email address

sg-sadeghianb@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Acupuncture Before The Start Of Anesthesia On Hemodynamic Criteria Changes On Preeclamptic Pregnant Women Candidate For Cesarean Section.

Public title

The Effect Of Acupuncture Before The Start Of Anesthesia On Intraoperative Hemodynamic Criteria Changes.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Have Informed Consent For Inclusion; Probability Of Beneficial Effects On People; Approval Of Preeclampsia By Obstetricians
Exclusion Criteria: Lack Of Consent; Coagulopathy; Diabetes; Epilepsy; Cancer; Acute Stroke

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 98

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee Of Tehran University Of Medical Sciences

Street address

4th Floor- Block 23 - 16 Azar St -Tehran - Iran

City

Tehran

Postal code

Approval date

2015-09-24, 1394/07/02

Ethics committee reference number

IR.TUMS.REC.1394.828

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O010

ICD-10 code description

Pre-Existing Hypertension Complicating Pregnancy, Childbirth And The Puerperium

Primary outcomes

1

Description

Heart Rate

Timepoint

Before Intervention- After Intervention

Method of measurement

Novin Saadat Machine

2

Description

Blood Pressure

Timepoint

Before Intervention- After Intervention

Method of measurement

Novin Saadat Machine

3

Description

Saturation Of Arterial Pressure

Timepoint

Before Intervention- After Intervention

Method of measurement

Novin Saadat Machine

Secondary outcomes

empty

Intervention groups

1

Description

In This Study, Acupuncture Is Considered By The Acupuncturist Using Acuahealth Device At Predetermined Points And Then The Process Of Intubation And Anesthesia Will Be Done. Both Control And Intervention Group Will Have The Same Type Of Surgery And Anesthesia.

Category

Treatment - Other

2

Description

In The Control Group Acupuncture Using Acuahealth Will Be Done At The Wrong Positions. The Anesthesia And Intubation Will Be Similar To The Intervention Group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Valiasr Hospital
Full name of responsible person
Doctor Negar Eftekhari
Street address
Caesarean Section Room, Tehran Valiasr Hospital,
Keshavarz BLVD, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian Scientific Acupuncture Association
Full name of responsible person
Golnaz Sadeghian
Street address
Khorramshahr St., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranian Scientific Acupuncture Association
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 Science
Full name of responsible person
Golnaz Sadeghian
Position
Student
Other areas of specialty/work
Street address
Emergency Childbirth Operating Room, Obstetric
Emergency Department, Imam Khomeini Hospital,
Keshavarz Blvd, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 6119 2386
Fax
Email

Sadeghiang@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
Doctor Negar Eftekhari
Position
Faculty Member Of Tehran University Of Medical
Sciences
Other areas of specialty/work
Street address
Emergency Childbirth Operating Room, Obstetric
Emergency Department, Imam Khomeini Hospital,
Keshavarz Blvd, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 6119 2386
Fax
Email
Negar_miloo@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University Of Medical Science.
Full name of responsible person
Golnaz Sadeghian
Position
student
Other areas of specialty/work
Street address
Emergency Childbirth Operating Room , Obstetric
Emergency Department , Imam Khomeini Hospital ,
Keshavarz Blvd , Tehran , Iran
City
Tehran
Postal code
Phone
+98 21 6119 2386
Fax
Email
Sadeghiang@yahoo.com
Web page address

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