

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Nimes Dopamine on prevention of early onset of LH in patients under IUI

Protocol summary

Study aim

Determination of the effect of pallidopin in preventing an early increase in LH in patients under IUI

Design

On the first or second day of meniscal cycle, patients underwent vaginal sonography to examine the follicle and thickness of the endometrium. Otherwise, the level of LH and estradiol was measured and injected from the second day of menstruation for five days based on age and weight between 75 and 150 units of hMG injection. On day 6, ovulation stimulation was performed again by patients under vaginal ultrasonography in terms of number or size of follicles. In the presence of at least two follicles 14 mm or higher, the nelfidipine tablet was administered to one group and another to another placebo. In the nausea diamine group, 30 mg tablets were taken three times a day for two days and sonography was performed again two days later. Hormone (RONAL-F) hMG and nelfidipine tablets continued until at least two 18 mm follicles were reached and ultrasound was performed every two days. In the presence of at least two 18 mm follicles, serum LH and serum estradiol levels were measured on the same day, and two hCG injections of the same day were injected at 5000 units and then IUI after 36 hours. In the case of LH Surge, when measured at least two 18 mm follicles, the serum level of LH measured was tripled. Safety and side effects The IUI regimen was regularly controlled to respond to optimal treatment and IUI time.

Settings and conduct

Tehran Mahdieh Hospital

Participants/Inclusion and exclusion criteria

20 < age < 40 Having both healthy ovaries in biographies and ultrasound evaluation Having at least one open tube in hysterosalpingography Diagnosis of infertility and the choice of IUI treatment by a physician

Intervention groups

Those who had the criteria for entering the study and were candidates for IUI

Main outcome variables

LH serum estrogen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141223020408N6**

Registration date: **2018-08-12, 1397/05/21**

Registration timing: **retrospective**

Last update: **2018-08-12, 1397/05/21**

Update count: **0**

Registration date

2018-08-12, 1397/05/21

Registrant information

Name

Robabeh Taheripanah

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Country

Iran (Islamic Republic of)

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+98 21 2243 2558

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-03-05, 1396/12/14

Trial completion date

empty

Scientific title

Effect of Nimes Dopamine on prevention of early onset of LH in patients under IUI

Public title

The effect of Nimudipine on LH

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged 20 to 40 years Having both healthy ovaries in biographies and ultrasound assessment Having at least one open tube in hysterosalpingography تشخیص توسط پزشک معالج IUI ناباروری و انتخاب روش درمانی 59/5000Diagnosis of infertility and the choice of IUI treatment by a physician

Exclusion criteria:**Age**

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random numbers of numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The investigator and the participants did not know how to get the drug and placebo

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics committee ofshahid beheshti University of Medical science

Street address

Tahrish hospital, Tajrish Ave

City

Tehran

Province

Tehran

Postal code

1653847955

Approval date

2018-01-14, 1396/10/24

Ethics committee reference number

IR.SBMU.MSP.RAC.1396.748

Health conditions studied

1

Description of health condition studied

INFERTILITI

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

prevention if LH surge

Timepoint

Before the intervention and the time of observation, at least two 18 mm follicles in ultrasound

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People who received Nimrodipine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mahdieh hospital

Full name of responsible person

Zahra razghandi

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Shoosh Square- Fadaeian Eslam Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
.
Proportion provided by this source
100
Public or private sector
Public
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
زهرا رازقندی
Position
پزشک
Latest degree
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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

What processes are involved for a request to access data/document

Comments