

# 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)

##### Phone

+98 21 2243 2558

##### Email address

taheripanahf@sbm.ac.ir

##### 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  
**Full name of responsible person**  
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Velenjak-Tehran  
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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  
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**Latest degree**  
Specialist  
**Other areas of specialty/work**

Gynecology and Obstetrics  
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## Person responsible for scientific inquiries

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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**