

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of ultrasonography and luteinization Hormone Surge Detection regarding the timing and outcomes of Intrauterine insemination in infertile couples.

Protocol summary

Summary

In this nonrandomized, not blinded, clinical trial study(phase 2),the purpose was to compare ultrasonography and luteinization Hormone Surge Detection for Timing and outcome of Intrauterine insemination;therefore, 190 patients were selected as candidates for Intrauterine Insemination (IUI) from 20.02.2013 to 19.02.2014 in the study. All patients with normal levels of Prolactin (PRL) & Thyroid-Stimulating Hormone (TSH) were included in the study (according to recent investigation). Females with Abnormal Uterine Bleeding were excluded from the study. In all patients, Transvaginal Ultrasonography (TVS) was performed on the third day of menstruation. Second control sonography was performed on the 11th day of cycle. In group A, from 11th day of menstruation on, patients started checking the urine sample daily at 4-10 Pm by urinary LH Surge kit. The checking has continued as long as a positive test was gained. Then 24 hours after gaining the positive test, the patient was referred for Intrauterine Insemination (IUI). In group B, on the 11th day of cycles, control with an ultrasound was done every other day. When 1-2 follicles of (16- 18 mm) were seen on ultrasound, Human Chorionic Gonadotropin (HCG) was injected and 36-40 hours later, Intrauterine Insemination (IUI) was performed. Two weeks after Intrauterine Insemination (IUI), BHCG was checked and if positive, pelvic sonography would be performed 4 weeks after IUI. Finally, pregnancy rate, ectopic pregnancy, and abortion were recorded and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121720358N1**
Registration date: **2015-10-16, 1394/07/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-16, 1394/07/24

Registrant information

Name

Nahal Nasehi

Name of organization / entity

Ahvaz Jondishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 7347

Email address

nasehi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of ultrasonography and luteinization Hormone Surge Detection regarding the timing and

outcomes of Intrauterine insemination in infertile couples.

Public title

A comparative study of ultrasound and urinary LH surge kit regarding the timing and outcomes of IUI

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 190 patient have been selected as participants for Intrauterine Insemination that have normal level of Prolactin (PRL) & Thyroid-Stimulating Hormone (TSH) (according to recent investigation).
Exclusion criteria: Female participants with abnormal Uterine bleeding were excluded from the study

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 190

Randomization (investigator's opinion)

Not randomized

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences
,Golestan Boulevard

City

Ahvaz

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

ajums.REC.1392.82

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97, N46

ICD-10 code description

Female infertility, Male infertility

Primary outcomes

1

Description

Pregnancy rate

Timepoint

two weeks after IUI

Method of measurement

positive or negative

Secondary outcomes

1

Description

Ectopic Pregnancy

Timepoint

4 weeks after IUI

Method of measurement

Pelvic ultrasound

2

Description

Abortion

Timepoint

4 weeks after IUI

Method of measurement

Pelvic ultrasound

Intervention groups

1

Description

In Interventional group urinary LH (luteal Hormone) kit, was used. 24 hours after positive kit, IUI (Intrauterine Insemination) was performed.

Category

Treatment - Other

2

Description

In control group, Transe vaginal ultra sound was used when 1 to 2 follicles 16-18 mm was seen on ultrasound 10000 units HCG injected. and the patient, was told for referring just 36-40 hours after doing IUI.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Ahvaz Imam Khomeini Hospital

Full name of responsible person

Dr. Nahal Nasehi

Street address

Ahvaz Imam Khomeini Hospital, Azadegan Avenue

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Boulevard

City

Ahvaz

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 of Ahvaz Jundishapur
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**

Department of Gynecology , Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Nahal Nasehi

Position

MD, Resident of Gynecology

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

Ahvaz Imam Khomeini Hospital, Azadegan Avenue

City

Ahvaz

Postal code**Phone**

+98 61 3333 7347

Fax**Email**

nahalnasehi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz Jundishapur University of Medical Science,
faculty of medicine

Full name of responsible person

Mahvash Zargar

Position

Assistant professor

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

Ahvaz Imam Khomeini Hospital, Azadegan Avenue

City

Ahvaz

Postal code**Phone**

+98 61 3222 2922

Fax**Email**

Dr.zargar@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nahal Nasehi

Position

MD, Resident of Gynecology

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

Ahvaz Imam Khomeini Hospital, Azadegan Avenue

City

Ahvaz

Postal code**Phone**

+98 61 3333 7347

Fax**Email**

nahalnasehi@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