# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Comparison of the effect of trigger ovulation HCG and HCG + oxytocin on creating the pregnancy

### Protocol summary

**Study aim**
Comparison of the effect of trigger ovulation HCG and HCG + Oxytocin on Creating the Pregnancy
**Design**
Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 50 infertile women
**Settings and conduct**
This study will be conducted with the aim of comparison the effect of HCG plus oxytocin and HCG alone on pregnancy rate in 50 infertile women. After inclusion in the study, using block randomization method with blocks of ten, the patients will be assigned into two groups; intervention group 1 receiving 5000 units HCG with 5 mg oxytocin intramuscularly and intervention group 2 receiving 5000 units HCG intramuscularly. 14 days after giving the drugs, the pregnancy will be evaluated by measuring the serum level of B-HCG and will be compared together.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: infertility more than 1 year; having normal uterine cavity and at least one normal fallopian tube Exclusion criterion: Infertility due to male factors
**Intervention groups**
Intervention group 1: receiving 5000 units HCG with 5 mg oxytocin intramuscularly Intervention group 2: receiving 5000 units HCG intramuscularly
**Main outcome variables**
Pregnancy

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20180307038987N1**
Registration date: **2018-11-01, 1397/08/10**
Registration timing: **registered_while_recruiting**
Last update: **2018-11-01, 1397/08/10**
Update count: **0**
**Registration date**
2018-11-01, 1397/08/10

**Registrant information**
**Name**
Shahnaz Nezamdoust
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 54 3329 5633
**Email address**
sh.135656.nez@zaums.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-09-06, 1397/06/15
**Expected recruitment end date**
2018-11-06, 1397/08/15
**Actual recruitment start date**
2018-09-23, 1397/07/01
**Actual recruitment end date**
2018-12-22, 1397/10/01
**Trial completion date**
2019-01-21, 1397/11/01

**Scientific title**
Comparison of the effect of trigger ovulation HCG and HCG + oxytocin on creating the pregnancy

**Public title**
The effect of HCG and HCG plus oxytocin on pregnancy rate
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**

Infertility more than 1 year Having normal uterine cavity and at least one normal fallopian tube

**Exclusion criteria:**

Infertility due to male factors

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

Actual sample size reached: **50**

More than 1 sample in each individual

Actual sample size in each individual: **1**

Blood Sample

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization with blocks of 10. The patients will be randomly assigned into 2 groups of 25. Considering the sample size of 50 ( 25 patients in HCG group and 25 patients in HCG plus oxytocin group) , 5 blocks with 10 people will be selected; in each block there will be 5 cards of HCG group and 5 cards of HCG plus oxytocin group. So by selecting each block, 5 people will be assigned into each group.

**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 Zahedan University of Medical Sciences

**Street address**

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2018-09-23, 1397/07/01

**Ethics committee reference number**

IR.ZAUMS.REC.1397.256

## Health conditions studied

### 1

**Description of health condition studied**

Infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

## Primary outcomes

### 1

**Description**

Pregnancy

**Timepoint**

14 days after giving the study drugs

**Method of measurement**

By measuring B-HCG serum level

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group 1: receiving 5000 units HCG with 5 mg oxytocin intramuscularly

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group 2: receiving 5000 units HCG intramuscularly

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Ali Ebne Abi Taleb Hospital

**Full name of responsible person**

Shahnaz Nezamdoost

**Street address**

Khalije Fars Blv, Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**
9816743111
**Phone**
+98 54 3329 5577
**Email**
sh.135656.nez@zaums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Zahedan University of Medical Sciences
**Full name of responsible person**
Mohsen Taheri
**Street address**
Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816743111
**Phone**
+98 54 3329 5721
**Email**
Dr.Taheri@zaums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Zahedan University of Medical Sciences
**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**
Zahedan University of Medical Sciences
**Full name of responsible person**
Shahnaz Nezamdoost
**Position**
Gynecology Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816743111
**Phone**
+98 54 3329 5575
**Email**
sh.135656.nez@zaums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Zahedan University of Medical Sciences
**Full name of responsible person**
Shahnaz Nezamdoost
**Position**
Gynecology Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816743111
**Phone**
+98 54 3329 5575
**Email**
sh.135656.nez@zaums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Zahedan University of Medical Sciences
**Full name of responsible person**
Shahnaz Nezamdoost
**Position**
Gynecology Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Gynecology and Obstetrics
**Street address**
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan
**City**
Zahedan

**Province**
Sistan-va-Balouchestan
**Postal code**
9816743111
**Phone**
+98 54 3329 5575
**Email**
sh.135656.nez@zaums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available