Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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

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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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
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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
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Person responsible for updating data

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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