

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the pregnancy rate following Intra Uterine Insemination 36 and 42 hours after human chorionic gonadotropin injection in infertile women

Protocol summary

Study aim

Comparison of the pregnancy rate following Intra Uterine Insemination 36 and 42 hours after human chorionic gonadotropin injection in infertile women

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 70 infertile women.

Settings and conduct

Using block randomization method with blocks of ten, the patients referred to Ali Ebne Abi Taleb hospital in Zahedan, will be assigned into two groups of Intra Uterine Insemination 36 and 42 hours after human chorionic gonadotropin injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal spermiogram; Body mass index of 18-30; Unexplained infertility Exclusion criteria: Bilateral tubal obstruction; Severe endometriosis; Uterine anomaly; Endocrine disorders such as Diabetes or thyroid gland disorders

Intervention groups

Intervention group 1: Injection of 0.5 cc sperm 36 hours after human chorionic gonadotropin Intervention group 2: Injection of 0.5 cc sperm 42 hours after human chorionic gonadotropin

Main outcome variables

Pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180428039442N1**

Registration date: **2018-05-12, 1397/02/22**

Registration timing: **prospective**

Last update: **2018-05-12, 1397/02/22**

Update count: **0**

Registration date

2018-05-12, 1397/02/22

Registrant information

Name

Mahbube Firooz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

dr.m.sirous@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the pregnancy rate following Intra Uterine Insemination 36 and 42 hours after human chorionic gonadotropin injection in infertile women

Public title

The effect of Intra Uterine Insemination time on pregnancy rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Normal spermiogram Body mass index of 18-30
Unexplained infertility Normal ovulation

Exclusion criteria:

Bilateral tubal obstruction Severe endometriosis Uterine anomaly
Endocrine disorders such as Diabetes or thyroid gland disorders

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization with blocks of ten

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

9916789547

Approval date

2018-01-14, 1396/10/24

Ethics committee reference number

IR.ZAUMS.REC.1396.347

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

Pregnancy rate

Timepoint

16 days after human chorionic gonadotropin injection

Method of measurement

By measuring beta-human chorionic gonadotropin (B-hCG)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Injection of 0.5 cc sperm 36 hours after human chorionic gonadotropin

Category

Treatment - Other

2

Description

Intervention group 2: Injection of 0.5 cc sperm 42 hours after human chorionic gonadotropin

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abi Taleb Hospital

Full name of responsible person

Mahbube Firooz

Street address

Khalije Fars Blv, Zahedan

City

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Postal code

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Phone

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Email
dr.m.sirous@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

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Postal code

9816743463

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

Mahbube Firooz

Position

Gynecology and Obstetrics Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Contact

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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

Not applicable

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