

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation of the Response to Treatment of HIV-1 Infected Men's Semen Sperm Washing Method in Pregnancy of Sero-Discordant Couples who Referred to Behavioral Diseases Consultation Center

Protocol summary

Summary

The main goal of this before-after clinical trial, is the evaluation of response to the treatment of HIV-1 positive men's sperm washing in HIV-1 sero-discordant couples who referred to behavioral diseases consultation center of Imam Khomeini Hospital, during 4 years. Sperm washing will do for 15 men who are living with HIV-1 and apply for having a baby, (the inclusion criteria: Being married; Men who living with HIV-1; The consent of both spouses; uninfected women and Exclusion criteria: lack of consent and Serum viral load of over 500 RNA copy number/ml). Fresh semen sample were washed and the Viral Load test is performed to assess sperm washing process, If the test's result is reported negative, the sample will send for Intra-Cytoplasmic Sperm Injection (ICSI). Washed sperm will be injected to ovum cytoplasm and embryo or embryos will be transferred to the mother's uterus. To ensure that mother has still remained uninfected, PCR HIV test is done in three periods: before the first- trimester; second-trimester and third-trimester of pregnancy. In case of detection of HIV infection in the mother, she immediately will be connected to the counseling center and will receive antiretroviral therapy according to national guideline.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604304076N19**
Registration date: **2016-06-27, 1395/04/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Minoos Mohraz

Name of organization / entity

Iranian Research Center for HIV/AIDS, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Response to Treatment of HIV-1 Infected Men's Semen Sperm Washing Method in Pregnancy of Sero-Discordant Couples who Referred to Behavioral Diseases Consultation Center

Public title

Evaluation of the Response to Treatment of HIV-1 Infected Men's Semen Sperm Washing Method in Pregnancy of Sero-Discordant Couples

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Being Married; Men who living with HIV-1; The consent of both spouses; Uninfected women.
Exclusion criteria: Lack of consent; Serum Viral load of over 500 RNA copy number/ ml.

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Central building of TUMS, Ghods St, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2016-03-08, 1394/12/18

Ethics committee reference number

IR.TUMS.REC.1394.2167

Health conditions studied

1

Description of health condition studied

HIV/AIDS

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases

2

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Mother infection status

Timepoint

Before the first-trimester, second-trimester and third-trimester of pregnancy.

Method of measurement

Laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this method, healthy and motile uninfected sperm cells are isolated from other cells. Semen samples will be loaded on a sperm washing medium gradient and then centrifuged. Finally healthy and motile uninfected sperm cells will deposit. For the next step, sperm pellet will be load on the bottom of a sterile tube which is filled with Ham's F10 and will be incubate for 30 minutes in 37 C temperature. Healthy and motile sperm cells will swim to the upper surface of medium, and concentrate there and will be isolated for next step. For evaluating of the effectiveness of the sperm washing, viral load counting (Real Time PCR) will be done on a part of the washed sperm pellet. If the test's result is reported negative (Undetectable), the sample will send for Intra-Cytoplasmic Sperm Injection (ICSI).

Category

Prevention

2

Description

Control group: This study is a single arm clinical trial that has no control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Triangular clinic for sexual and behavioral diseases,
Imam Khomeini Hospital

Full name of responsible person

Dr. Minoo Mohraz

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Deputy of Tehran University of Medical
Sciences

Full name of responsible person

Dr Younesian

Street address

Ghods Avn, Keshavarz Blvd

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy of Tehran 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**

Iranian research Center for HIV AIDS (IRCHA)

Full name of responsible person

Dr. Minoo Mohraz

Position

Head of IRCHA

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

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Iranian Research Center for HIV AIDS

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Position

Professor

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Iranian Research Center for HIV/AIDS

Full name of responsible person

Farzaneh Vakil Ghahani

Position

Msc

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Fax**Email****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