Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of pentoxifylline on sperm structure ,embryo morphokinetics resulting from these sperms and clinical outcomes compared to the control group in azoospermic patients

Protocol summary

Study aim
Assessment of the effect of in vitro application of pentoxifylline on ultrastructure and DNA of spermatozoa, embryo morphokinetics and clinical outcomes in azoospermic patients

Design
Clinical trial with parallel control and intervention groups, no blinding, study on 40 azoosperm patients

Settings and conduct
Among the patients referring to Yazd Infertility Center, 40 testicular samples randomly will be selected in patients with azoospermia. Male factor infertility was the main diagnosis for all couples and all patients will receive written consent.to be involved in the study protocol.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Non obstructive azoospermia patient younger than 50 years and more than 50 number sperm women less than 40 years old without any Infertility problems Exclusion criteria: HIV- positive patient with any pathology Patients with very low sperm count

Intervention groups
Each person's sperm sample is divided into two parts: control group:Addition of 3.6 mmol pentoxifylline to a drop of containing sperm sample interventional group: No intervention is made

Main outcome variables
chemical pregnancy rate clinical pregnancy rate

General information

Reason for update
Azoosperm patients included in the study with both fresh and frozen samples.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200705048020N1**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **prospective**

Last update: **2022-04-19, 1401/01/30**
Update count: **3**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Maryam Mahaldashtian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 4333 4693

Email address
mahaldashtian.m@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-26, 1399/12/08

Expected recruitment end date
2022-02-28, 1400/12/09

Actual recruitment start date
2021-03-09, 1399/12/19

Actual recruitment end date
2022-02-28, 1400/12/09

Trial completion date
2022-02-28, 1400/12/09

Scientific title
Comparison of the effect of pentoxifylline on sperm structure ,embryo morphokinetics resulting from these sperms and clinical outcomes compared to the control group in azoospermic patients

Public title

Evaluation the effect of Pentoxifylline on spermatozoa of Azoospermic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All non obstructive azoospermia patients less than 50 years old and more than 50 number sperm women less than 40 years old without any Infertility problems

Exclusion criteria:

HIV- positive patient with any pathology Patients with very low sperm count women more than 40 years old Couples who also have problems with female infertility

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each person's sperm sample is divided into two parts: control group:Addition of 3.6 mmol pentoxifylline to a drop of containing sperm sample interventional group: No intervention is made

Actual sample size reached: **57**

Randomization (investigator's opinion)

N/A

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 Yazd University of Medical Sciences

Street address

Research Institute of Reproductive Sciences,Bouali St., Safaieh

City

yazd

Province

Yazd

Postal code

8916877391

Approval date

2019-08-26, 1398/06/04

Ethics committee reference number

IR.SSU.RSI.REC.1398.013

Health conditions studied

1

Description of health condition studied

azoospermia

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Fertilization rate

Timepoint

One day after assisted artificial insemination

Method of measurement

formation of 2 pronucleous

2

Description

Embryo formation rate

Timepoint

3 days after assisting artificial insemination

Method of measurement

8 cell embryo formation

3

Description

Embryo morphokinetic rate

Timepoint

From the time of pronucleous formation until the time of embryo transfer to the mother's uterus

Method of measurement

Time Lapse Incubator

4

Description

Chemical pregnancy rate

Timepoint

One week after the embryo transfer to the uterus

Method of measurement

Blood βHCG Measurement

Secondary outcomes

1

Description

Clinical pregnancy rate

Timepoint
7 weeks after embryo transfer to the uterus
Method of measurement
Assessment of cardiovascular formation using ultrasound examination

Intervention groups

1

Description
Intervention group: Addition of 3.6 mmol pentoxifylline to a drop of containing sperm sample and selection of motile sperm
Category
Treatment - Drugs

2

Description
Control group: No intervention is made
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Research Center-Shahid Sadoughi University of Medical Sciences, Yazd
Full name of responsible person
Abbas Aflatoonian
Street address
Bouali Street, Safaieh, Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
mahaldashtian.m@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
masoud mirzaei
Street address
Bouali Street,Safaieh
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
mahaldashtian.m@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
mohammad ali khalili
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Bouali street,Safaieh
City
yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 8119
Email
khalili59@hotmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
mohammad ali khalili
Position
professor
Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Bouali street,Safaieh

City

yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Email

khalili59@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

maryam mahaldashtian

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Bouali street,Safaieh

City

yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Email

mahaldashtian.m@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Data: 1) Fertility rate, by examining the formation of proonucleus in the egg cell 2) Checking the embryo quality and morphokinetic using time lapse system and calculating the time related to the process of cell division of the embryo 3) Checking the chemical and clinical pregnancy rates respectively one week and 7 weeks after embryo transfer

When the data will become available and for how long

Up to one year after publication of the article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

With the re-consent of the participant and the researcher responsible of the project

From where data/document is obtainable

mohammad ali khalili 09133570876
khalili59@hotmail.com

What processes are involved for a request to access data/document

Send a request via email to the responsible researcher

Comments