

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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  $\beta$ HCG 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

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**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**

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**Phone**

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**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 pronucleus 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**