

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of the effect of red grape seed extract on idiopathic infertile male patients' spermogram at Royan infertility center in 2010

#### Protocol summary

##### Summary

The purpose of this study is to evaluate the effect of red grape seed extract on the semen parameters of men who involved idiopathic infertility. The cases consist of about 50 idiopathic infertile men, aged between 20-45 years old, who refer to Royan infertility center in 2010. This is a parallel group randomized controlled trial. The selected patients will be assigned in 2 groups as intervention and control. At first, ROS level in semen plasma and 2 semen analysis will be measured and then all patients will receive their medications (medicine or placebo) for three months. Then, ROS level and 2 semen analysis will be measured again after the treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201010034861N1**  
Registration date: **2010-10-25, 1389/08/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-10-25, 1389/08/03

##### Registrant information

###### Name

Reza Salman Yazdi

###### Name of organization / entity

Royan Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2230 6478

###### Email address

r.salmanyazdi@royaninstitute.org

##### Recruitment status

**Recruitment complete**

##### Funding source

Royan Institute, Urology & Nephrology Research Center, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2010-05-22, 1389/03/01

##### Expected recruitment end date

2011-03-19, 1389/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of red grape seed extract on idiopathic infertile male patients' spermogram at Royan infertility center in 2010

##### Public title

The effect of red grape seed extract on human semen parameters

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Oligozoospermia with sperm count 5-20 million/ml and astenozoospermia with progressive motility less than 40% Exclusion criteria: Explained infertility (e.g. hormonal disorders, epididimis canal obstruction, epididimorchitis,...) smoking, drug or alcohol addiction, diabetes, renal disorders (creatinine more than 2.0 times), chronic liver diseases (transaminase more than twice as much normal), varicocele, infectious diseases indicated with fever and leukocytosis, sexual arousing-drugs consumption

##### Age

From **20 years** old to **45 years** old

##### Gender

Male

## Phase

0

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Royan Institute

##### Street address

No.12 Hafez st., bani-hashem st., Resalat Ave.,

##### City

Tehran

##### Postal code

16656-59911

#### Approval date

2010-09-28, 1389/07/06

#### Ethics committee reference number

006/89/5

## Health conditions studied

### 1

#### Description of health condition studied

Male Infertility

#### ICD-10 code

N46

#### ICD-10 code description

Male Infertility

## Primary outcomes

### 1

#### Description

Sperm Motility

#### Timepoint

before intervention and a week after intervention

#### Method of measurement

Motility velocity and percentage

### 2

#### Description

ROS (Reactive Oxygen Species) levels

#### Timepoint

before intervention and a week after intervention

#### Method of measurement

Concentration assay by chemiluminescence method

### 3

#### Description

Sperm Concentration

#### Timepoint

before intervention and a week after intervention

#### Method of measurement

Counting the sperms

## Secondary outcomes

### 1

#### Description

FSH level

#### Timepoint

Before intervention and a week after intervention

#### Method of measurement

ELISA

### 2

#### Description

LH level

#### Timepoint

Before intervention and a week after intervention

#### Method of measurement

ELISA

### 3

#### Description

Testosterone level

#### Timepoint

Before intervention and a week after intervention

#### Method of measurement

ELISA

## Intervention groups

### 1

#### Description

Intervention: Red Grape Seed Extract, Capsule 300mg, Twice/day, for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Control: Placebo, Capsule 300mg, Twice/day, for 3

months  
**Category**  
Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Royan Institute

**Full name of responsible person**

Dr. Reza Salman Yazdi

**Street address**

No.12, East-hafez St., Bani-hashem St., Resalat ave.,

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Royan Institute

**Full name of responsible person**

Dr. Abdol-Hoseyn Shahverdy

**Street address**

No.12, East-hafez St., Bani-hashem st., Resalat Ave.,

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Royan Institute

**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**

Royan Institute

**Full name of responsible person**

Reza Salman Yazdi

**Position**

Doctorate, member of Royan faculty

**Other areas of specialty/work**

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**Web page address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Email**

r\_salman\_yazdi@yahoo.com

**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*