

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 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

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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.,

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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.,

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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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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