Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Study of Condensyl supplementary on sperm parameters, chromatin structure, fertilization rate and embryo quality in assisted reproduction technologies resistant couples

Protocol summary

Summary

Objectives: The aim of this study is to evaluate the effect of the Condensyl™ treatment in the ART (Assisted Reproduction Technologies)-resistant patients, in improving the sperm parameters, chromatin integrity, sperm condensation and clinical outcome with cooperation several Fertility Centers. Design: This study include 100 infertile couples with ART -resistant that referred to the IFIC (Isfahan Fertility and Infertility Center) for ART procedure. These patients have generally at least a failure in ART cycle. All couples are informed regarding the study and consent forms are signed. This study is designed similar to a single blind clinical trial that analyzer is blinded to study. Major Inclusion and Exclusion criteria: Inclusion criteria: Primary male factor infertility and either a DFI (DNA Fragmentation Index) and SDI (Sperm Decondensation Index) higher than 10%. Exclusion criteria: Females factor infertility, female with higher than 40 years, less than 6 matured MII oocytes and thick endometrium. Intervention: Male participants are administrated 1 or 2 Condensyl™ tablets per day for 3 to 6 months prior to their ART cycle. Main outcome measures (variables): Sperm parameters (according to the WHO-2010), sperm DNA fragmentation (TUNEL assay) and decondensation (aniline blue staining) are compared before and after the Condensyl™ treatment. Fertilization rate and embryo quality were compared with previous ART cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510207223N6**
Registration date: **2015-10-30, 1394/08/08**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-10-30, 1394/08/08

Registrant information

Name

Mohammad Hossein Nasr-Esfahani

Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

Country

Iran (Islamic Republic of)

Phone

+98 31 9501 5688

Email address

mh_nasr@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2015-11-26, 1394/09/05

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Condensyl supplementary on sperm parameters, chromatin structure, fertilization rate and embryo quality in assisted reproduction technologies resistant couples

Public title

Study of Condensyl supplementary on sperm function and clinical outcome in assisted reproduction technologies resistant couples

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Primary male factor infertility (according to the WHO-2010) and either a DFI (DNA Fragmentation Index) and SDI (Sperm Decondensation Index) higher than 10%. Exclusion criteria: Females factor infertility, female with higher than 40 years, less than 6 matured MII oocytes and thick endometrium.

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Royan Institute

Street address
Royan Institute ,Hafez St, Banihashem St, Resalat Ave, Tehran, Iran,

City
Tehran

Postal code

Approval date
2015-10-05, 1394/07/13

Ethics committee reference number
IR.ACECR.ROYAN.REC.1394.9

Health conditions studied

1

Description of health condition studied
Male factor infertility

ICD-10 code
N46

ICD-10 code description
Male infertility

Primary outcomes

1

Description
Sperm concentration

Timepoint
Before and after the Condensyl™ treatment (3-6 month)

Method of measurement
Optical microscope, based WHO criteria

2

Description
Sperm motility

Timepoint
Before and after the Condensyl™ treatment (3-6 month)

Method of measurement
Optical microscope, based WHO criteria

3

Description
Sperm morphology

Timepoint
Before and after the Condensyl™ treatment (3-6 month)

Method of measurement
Optical microscope, based WHO criteria

4

Description
Sperm decondensation

Timepoint
Before and after the Condensyl™ treatment (3-6 month)

Method of measurement
Optical microscope

5

Description
DNA fragmentation

Timepoint
Before and after the Condensyl™ treatment (3-6 month)

Method of measurement
Fluorescent microscope

6

Description
Fertilization rate

Timepoint
16 - 20 h after insemination/injection

Method of measurement
View of two pronuclei with invert microscope

7

Description
Quality of embryo
Timepoint
Three days after insemination/injection
Method of measurement
Using a three-point scoring system including fragmentation rate, number of blastomere, shape and size

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Male participants are administrated 1 or 2 Condensyl™ tablets per day for 3 to 6 months prior to current ART cycle. Sperm parameters, DNA fragmentation and decondensation are compared before and after the Condensyl™ treatment. Combination (Condensyl™) contained of opuntia fig fruits (100 mg) delivering tailored amounts of quercetin (0.05 mg) and betalain (0.001 mg) plus a mix of Group B vitamins: B2 (1.4 mg), B3 (16 mg), B6 (1.4 mg), B9 (400 µg), B12 (2.5 µg). The administered product also contained zinc (12.5 mg) and small doses of N-acetylcysteine (250 mg) and vitamin E (12 mg).
Category
Treatment - Drugs

2

Description
Control group: Failed previous ART cycles of participated infertile men.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Fertility and Infertility Center
Full name of responsible person
Mohammad Hossein Nasr-Esfahani
Street address
Fertility and Infertility Center ,Salman Farsi St, Isfahan, Iran,
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Royan Institute
Full name of responsible person
Abdolhossein Shahverdi
Street address
Royan Institute ,Hafez St, Banihashem St, Resalat Ave, Tehran, Iran,
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 (Royan Institute for Biotechnology)
Full name of responsible person
Mohammad Hossein Nasr-Esfahani
Position
Professor
Other areas of specialty/work
Street address
Royan Institute for Biotechnology ,Royan St, Salman St, Khorasgan, Isfahan, Iran,
City
Isfahan
Postal code
Phone
+98 31 9501 5688
Fax
Email
mh_nasr@med.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Royan Institute (Royan Institute for Biotechnology)
Full name of responsible person
Mohammad Hossein Nasr-Esfahani

Position
Professor
Other areas of specialty/work
Street address
Royan Institute for Biotechnology ,Royan St, Salman St, Khorasgan, Isfahan, Iran,
City
Isfahan
Postal code
Phone
+98 31 9501 5688
Fax
Email
mh_nasr@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Royan Institute (Royan Institute for Biotechnology
Full name of responsible person
Mohammad Hossein Nasr Esfahani
Position
Professor
Other areas of specialty/work
Street address
Royan Institute for Biotechnology ,Royan St, Salman St, Khorasgan, Isfahan, Iran,
City
Isfahan
Postal code
Phone
+98 31 9501 5688
Fax
Email
mh_nasr@med.mui.ac.ir
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