Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of varicocelectomy on ARTs indications on base of Kruger strict morphology test

Protocol summary

Summary

The purpose of this study was to evaluate the efficacy of varicocelectomy on improving ARTs (assisted reproductive techniques) indications on the base of Kruger strict morphology test. Method and materials: For assessing of improving ART levels after varicocelectomy in a randomized and case –control study we compared the results of sperm analysis parameters between 67 infertile operated patients with 71 matched no operated groups in one-year duration. All subjects included in this study (both study and control groups) had clinical varicoceles and were infertile, we excluded varicocele re-operated, with known infertility risk factors, singles, fertile or fertility history men, and wives older than 35-year-olds. Intervention: sub- Inguinal varicocelectomy with magnification in the study group. The primary outcome in this study was spermogram parameters (count, motility, and sperm morphology on Kruger standards) after the intervention, and their wife pregnancy was the secondary outcome at the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611091981N7**
Registration date: **2017-05-06, 1396/02/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-06, 1396/02/16

Registrant information

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Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Physiology Research Center, Kerman University of Medical Sciences

Expected recruitment start date

2010-12-31, 1389/10/10

Expected recruitment end date

2013-12-31, 1392/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of varicocelectomy on ARTs indications on base of Kruger strict morphology test

Public title

varicocelectomy and ARTs indications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male gender; married; being infertile; clinical dignosis for varicocele. Exclusion criteria: single; fertile; known other infertility factors.

Age

From **22 years** old to **28 years** old

Gender

Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **255**
Randomization (investigator's opinion)
Randomized
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
Ethical Committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences
City
Kerman
Postal code
Approval date
2017-04-23, 1396/02/03
Ethics committee reference number
IR.KMU.REC.1396.03

Health conditions studied

1

Description of health condition studied
Male infertility
ICD-10 code
I86.1
ICD-10 code description
Scrotal varices

Primary outcomes

1

Description
spermogram
Timepoint
spermogram improvment
Method of measurement
spermanalysis kruger test

Secondary outcomes

1

Description
wife pregnancy
Timepoint
12 months
Method of measurement
sonograhy

Intervention groups

1

Description
watch full in control group with recommendations for avoiding known infertility risk factors
Category
Behavior

2

Description
sub inguinal varicocelectomy by magnification in intervention group with recommendations for avoiding known infertility risk factors
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
urology department, Bahonar Hospital, Kerman
Full name of responsible person
Street address
City
kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Hamid Najafi
Street address
Physiology Research Center, Kerman University of Medical Sciences
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kerman University of Medical Sciences
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
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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