

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of adjuvant oral vitamin C therapy after varicocele surgery for improvement in sperm formation in infertile men

Protocol summary

Summary

In this randomized double blind clinical trial, the effect of adjuvant treatment of vitamin C on improvement in spermatogenesis after varicocele surgery is evaluated. All men with infertility and varicocele who attend Vali Asr Hospital of Arak or the private clinics of the executives of the study will be examined. In case of palpable varicocele in physical examination and accompanying abnormality in count, motility, or morphology of sperms in two separate semen analyses, they become candidates for surgery. Patients aged 18 to 50 who do not have azoospermia, underlying diseases, addiction to tobacco or opioids, active or chronic genito-urinary tract infections, history of peptic ulcer, or previous reaction to vitamin C will be recruited in our study. Those who do not consent to continue the study, do not come back for follow up visits, demonstrate side effects due to vitamin C, or become afflicted with late complications such as hydrocele, recurrence of varicocele, or testis atrophy will be excluded from the study. After surgery, patients are randomly divided into two groups and group one or the controls receive capsules filled with starch as placebo and group 2 receive capsules containing 500 mg of vitamin C in two daily doses. Three months after the surgery 2 separate semen analyses will be performed and the results before and after the surgery in regards to sperm count, motility, and morphology in the two groups are recorded and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103042134N2**

Registration date: **2011-12-27, 1390/10/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-27, 1390/10/06

Registrant information

Name

Ali Cyrus

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 1888 1041

Email address

cyrus@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2011-05-04, 1390/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adjuvant oral vitamin C therapy after varicocele surgery for improvement in sperm formation in infertile men

Public title

The effect of adjuvant vitamin C after varicocele surgery for improvement in sperm formation in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Palpable varicocele (grade 2 or 3) in physical examination; Abnormality in count, motility, or morphology of sperm in two separate semen analyses based on WHO criteria; No azoospermia; No major underlying disease such as: diabetes or hormonal abnormalities based on history and physical examination; Not smoker or addicted to any recreational drugs; Not using any drugs or supplements on a regular basis; Age between 18-50 years; Weight between 50-100 kg; No active or chronic genitourinary infection based on history, physical examination, urine analysis, and semen analysis; No previous history of peptic ulcer disease or vitamin C intolerance
Exclusion criteria: Patients' unwillingness to continue participation; Not attending follow up visits; Incorrect utilization of the capsules; Occurrence of side effects due to capsules; Late complications of surgery such as hydrocele, recurrence of varicocele, or testis atrophy; Commencement of smoking or addiction during the follow up

Age
From **18 years** old to **50 years** old

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

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

Ethics Committee of Arak University of Medical Sciences

Street address

Pardis Complex, Basij Square, Enghelab Square, Taleghani Ave

City

Arak

Postal code

Approval date

2010-02-20, 1388/12/01

Ethics committee reference number

88-71-6

Health conditions studied

1

Description of health condition studied

Varicocele

ICD-10 code

186.1

ICD-10 code description

Scrotal varices

2

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 and 3 months after the surgery

Method of measurement

Mean percent of motile sperm class A+B in two separate semen analyses

2

Description

Sperm count

Timepoint

Before and 3 months after the surgery

Method of measurement

Mean concentration of sperm in two separate semen analyses

3

Description

Sperm morphology

Timepoint

Before and 3 months after the surgery

Method of measurement

Mean percent of sperm with normal morphology based on WHO criteria in two separate semen analyses

Secondary outcomes

1

Description

Side effects

Timepoint

During the 3-month period of follow up

Method of measurement

Bases on patients' report on monthly visits

Intervention groups**1****Description**

The control group receives two daily doses of starch-filled capsules as placebo, for 3 months after the surgery.

Category

Placebo

2**Description**

The control group receives two daily doses of capsules filled with 500 mg of vitamin C (Osveh pharmaceuticals- Ref No. 1228038410) for 3 months after the surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arak Vali Asr Hospital

Full name of responsible person

Dr. Ali Cyrus

Street address

Department of Surgery, Vali-Asr Hospital, Vali-Asr Square

City

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr. Saeed Changizie Ashtiani

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Pardis Complex, Basij Square, Enghelab Square, Taleghani Ave

City

Arak

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Arak 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****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr. Ali Cyrus

Position

Urologist/Associate professor

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

Name of organization / entity

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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