

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of Spirulina microalgae on Semen Parameters in Men with Idiopathic Infertility

Protocol summary

Summary

Based on several claims on the positive effect of spirulina microalgae in the treatment of male infertility, this study is aimed to assess the effect of spirulina microalgae on semen parameters in men with idiopathic infertility. Inclusion criteria included idiopathic infertility (abnormal sperm motility and morphology based on WHO index), evidence of wife fertility, and age 20-40 year. The patients with medical situation or surgery that can cause infertility, previous history of chemotherapy, history of varicocele of cryptorchidism, body mass index 30kg/m² or greater, alcohol, drugs or other substance abuse, history of androgen or anti-androgen drugs consumption, severe kidney insufficiency (serum creatinine greater than 2.0 mg/dl), severe liver insufficiency (serum bilirubin greater than 2.0 mg/dl), azoospermia, and immune-suppressant drugs usage were excluded. Forty males with idiopathic infertility will be randomly assigned into two groups. The intervention group will receive 2g spirulina plus standard therapy for idiopathic infertility (L-carnitine, zinc sulfate, and 50mg/day clomiphene) for 3 months whereas the control group will just receive the standard regimen for 3 months. Sperm motility, morphology, and count will be assessed at baseline and 3 months later as a primary outcome. Only analysts are blinded in this study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081320441N5**
Registration date: **2016-09-10, 1395/06/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-10, 1395/06/20

Registrant information

Name

Farzaneh Foroughinia

Name of organization / entity

Shiraz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, international branch

Expected recruitment start date

2016-01-24, 1394/11/04

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Spirulina microalgae on Semen Parameters in Men with Idiopathic Infertility

Public title

Effect of Spirulina microalgae on Semen Parameters in Men with Infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with idiopathic infertility (abnormal sperm motility and morphology based on WHO index); evidence of wife fertility; age 20-40 year.

Exclusion criteria: medical situation or surgery that can cause infertility; previous history of chemotherapy; history of varicocele or cryptorchidism; BMI 30kg/m² or greater; alcohol, drugs or other substance abuse; treatment with androgen or anti-androgen drugs; severe kidney insufficiency (serum creatinine greater than 2.0 mg/dl); severe liver insufficiency (serum bilirubin greater than 2.0 mg/dl); azoospermia; treatment with immune-suppressant drugs

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

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand avenue, Shiraz, Fars, Iran

City

Shiraz

Postal code

Approval date

2016-01-24, 1394/11/04

Ethics committee reference number

IR.SUMS.REC.1394.187

Health conditions studied

1

Description of health condition studied

Idiopathic male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Sperm motility

Timepoint

Baseline and 3 months later

Method of measurement

Laboratory analysis

2

Description

Sperm morphology

Timepoint

Baseline and 3 months later

Method of measurement

Laboratory analysis

3

Description

Sperm count

Timepoint

Baseline and 3 months later

Method of measurement

Laboratory analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: administration of 2 g spirulina daily plus standard regimen for the treatment of idiopathic male infertility for 3 months

Category

Treatment - Drugs

2

Description

Control: just standard regimen for treatment of idiopathic male infertility (L-carnitine, zinc sulfate, clomiphene 50mg/day) for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faghihi hospital
Full name of responsible person
Farzaneh Foroughinia
Street address
Faghihi hospital, Zand Avenue, Shiraz, Fars, Iran
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2

Recruitment center
Name of recruitment center
Motahari polyclinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences, international branch
Full name of responsible person
Ali Poostforoosh Fard
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Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand avenue, Shiraz, Fars, Iran
City
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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
Shiraz University of Medical Sciences, international branch
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
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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>