

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The effect of myo-inositol and N-acetyl-L-cysteine on improving of the quantitative and qualitative indices of prepared sperms for using in Assisted Reproductive Technology (IVF/ICSI)

Protocol summary

Study aim

determination of the effect of myo-inositol and N-acetyl-L-cysteine on improving of the quantitative and qualitative indices of prepared sperms for using in Assisted Reproductive Technology (IVF/ICSI)

Design

This study is a clinical trial with a control group, parallel groups, No Blind and No Randomization.

Settings and conduct

This study was performed on 63 infertile patients due to male factors referred to Hazrat Zahra infertility treatment center in Shahrekord. After semen sampling and preparation, before and after the intervention, all of the sperm biological parameters as well as all the sperm fertility indexes using Makler lam (Contrast phase microscope) and SQA-V gold version 2.48 sperm analyzer were examined by one person (Andrology expert) and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertility history for at least 12 months, Infertility with male causes, Non-use of minerals, multivitamins and any fertility enhancer drug during the last three months. Exclusion criteria: Using alcoholic drinks or Unauthorized compounds and drugs (Opiate, Psychotropic drugs, Bodybuilding compounds, Antipsychotics, Sedative)

Intervention groups

The prepared sperm sample is divided into four parts: Treatment group 1: One portion of the sample is incubated with myo-inositol drug (INOFOLIC Sachet, Parsian health) at a concentration of 2 mg / ml at 37 ° C for 20 minutes. Treatment group 2: One portion of the sample is incubated with NAC Antioxidant drug (600 mg Sachet, Iran daro) for 20 minutes. Treatment group 3: One portion of the sample is incubated with myovinitsil + NAC for 20 minutes. Control group: The final portion of the sample is incubated without any drug for 20 minutes

at 37 ° C.

Main outcome variables

Sperm viability, sperm morphology, total sperm motility, SMI, PMSCa, PMSCb

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042618N2**

Registration date: **2019-03-26, 1398/01/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-26, 1398/01/06**

Update count: **0**

Registration date

2019-03-26, 1398/01/06

Registrant information

Name

najme bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 8235

Email address

st_bagherin@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of myo-inositol and N-acetyl-L-cysteine on improving of the quantitative and qualitative indices of prepared sperms for using in Assisted Reproductive Technology (IVF/ICSI)

Public title

The effect of myo-inositol and N-acetyl-L-cysteine on prepared sperms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertility history for at least 12 months Infertility with male causes Non-use of minerals, multivitamins and any fertility enhancer drug during the last three months

Exclusion criteria:

Using alcoholic drinks or Unauthorized compounds and drugs(Opiate, Psychotropic drugs, Bodybuilding compounds, Antipsychotics, Sedative)

Age

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

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

N/A

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

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Building No. 2,

University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713492

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.SKUMS.REC.1396.190

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 viability

Timepoint

Before the proximity to medication, at the end of the incubation period

Method of measurement

Trypan blue staining and contrast phase microscope

2

Description

Sperm morphology

Timepoint

Before the proximity to medication, at the end of the incubation period

Method of measurement

Contrast phase microscope, Sperm analyzer device

3

Description

total sperm motility

Timepoint

Before the proximity to medication, at the end of the incubation period

Method of measurement

Contrast phase microscope, Sperm analyzer device

4

Description

SMI

Timepoint

Before the proximity to medication, at the end of the incubation period

Method of measurement

Sperm analyzer device

5

Description

PMSCa

Timepoint

Before the proximity to medication, at the end of the incubation period

Method of measurement

Contrast phase microscope, Sperm analyzer device

6

Description

PMSCb

Timepoint

Before the proximity to medication, at the end of the incubation period

Method of measurement

Contrast phase microscope, Sperm analyzer device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: is incubated with myo-inositol drug(INOFOLIC Sachet, Parsian health) at a concentration of 2 mg / ml at 37 ° C for 20 minutes

Category

Treatment - Drugs

2

Description

Intervention group: is incubated with NAC(600 mg Sachet, Iran daro)Antioxidant drug at 37 ° C for 20 minutes.

Category

Treatment - Drugs

3

Description

Intervention group: is incubated with myovinitil + NAC at 37 ° C for 20 minutes.

Category

Treatment - Drugs

4

Description

Control group: is incubated without any drug for 20 minutes at 37 ° C.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Hazrat Zahra Infertility Center

Full name of responsible person

Maryam Nemati

Street address

Infertility Center of Hazrat Zahra, Next to the Imam Hassan mosque, West Saadi Street, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816866659

Phone

+98 38 3222 0478

Email

mertanem@yahoo.co.uk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Seyed Kamal Solati

Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

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Phone

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Email

kamal_solati@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Maryam Nemati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Shahrekord University of Medical Sciences, Building No. 2, University headquarters, Ayatollah Kashani Blvd

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Email

nemati.m2016@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Maryam Nemati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Maryam Nemati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Phone

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Email

nemati.m2016@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

data will be kept private.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Using data to complete studies

From where data/document is obtainable

Shahre-kord University of Medical Sciences, Dr Maryam Nemati

What processes are involved for a request to access data/document

after deliberation of researcher request and presentation of adequate documents, it will be able to exhibit.

Comments

