

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Efficacy Assessment of Mannitol vs Albumin in Management of Ovarian Hyperstimulation Syndrome - A randomized controlled trial

Protocol summary

Study aim

Achieving cheaper, more affordable, and safe drug therapy method with fewer side effects for managing severe ovarian hyperstimulation syndrome.

Design

Randomized controlled trial, community based and pragmatic, with parallel groups, blind, randomized

Settings and conduct

Sarem Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Severe ovarian hyperstimulation syndrome based on the classification of Rizg and Aboulghar. Exclusion criteria: Patient's dissatisfaction with the study; occurrence/history of allergy to the drug.

Intervention groups

Intervention group: 500-mL mannitol 20% is infused with 500 mL D5NS solution through a Y-site over 4 hours. Pulmonary auscultation, abdominal girth, renal function and hemoconcentration are monitored, after 4 hours of infusion, 500-mL D5NS was infused over 30-60 minutes. The second infusion was not performed if examinations indicated progressive fluid retention in the body. Control group: 1 L of normal saline is initially infused over 1 hour. If the patient has an appreciable urine output (50 ml over the hour), an IV fluid "maintenance" is initiated. 5% dextrose in normal saline (D5NS) 125-150 mL/h, urine output is assessed every 4 hours, and hematocrit (Hct) is determined 4 hours after the start of IV hydration to ensure that hemoconcentration is reversing. If there is inadequate response in urine output from the initial 1-L fluid bolus, an IV infusion of 250 mL of 20% albumin solution is given over 4 hours with a recheck of Hct 1 hour after the infusion. This protocol is repeated in a serial fashion (every 4 to 12 hours) until the Hct is brought within 6%-38%.

Main outcome variables

Abdominal girth, weight, fluid intake/output, hematocrit, serum sodium and potassium, serum creatinine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180305038953N1**

Registration date: **2018-05-15, 1397/02/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-15, 1397/02/25**

Update count: **0**

Registration date

2018-05-15, 1397/02/25

Registrant information

Name

Maryam Namdar Khanzadeh

Name of organization / entity

Sarem Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 4467 0888

Email address

dr.m_namdar@saremcrc.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy Assessment of Mannitol vs Albumin in Management of Ovarian Hyperstimulation Syndrome – A randomized controlled trial

Public title

Mannitol efficacy in ovarian hyper stimulation syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Severe ovarian hyper stimulation syndrome

Exclusion criteria:

Patient dissatisfaction to participate in the study History of / sensitivity to the used drug

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block, individual randomization, using software; not blinded.

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 Iran University of medical Sciences (IUMS)

Street address

Iran University of medical Sciences (IUMS), Hemmat Highway, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2017-12-04, 1396/09/13

Ethics committee reference number

IR.IUMS.REC.1396.23099608825

Health conditions studied

1

Description of health condition studied

Ovarian hyper stimulation syndrome

ICD-10 code

N98.1

ICD-10 code description

Hyperstimulation of ovaries

Primary outcomes

1

Description

Abdominal girth

Timepoint

Every morning

Method of measurement

Centimeter

2

Description

Weight

Timepoint

Every morning

Method of measurement

Digital scale; kilogram

3

Description

Hematocrite

Timepoint

Every 8 to 24 hours based on clinical severity of symptoms

Method of measurement

Colormetry; Percent

4

Description

Serum creatinine

Timepoint

Every 8 to 24 hours based on clinical severity of symptoms

Method of measurement

Milligram/deciliter

5

Description

Serum sodium level

Timepoint

Every 8 to 24 hours based on clinical severity of symptoms

Method of measurement

Ion Selective Electrode (ISE); millimol/milliliter

6

Description

Serum potassium level

Timepoint

Every 8 to 24 hours based on clinical severity of symptoms

Method of measurement

Ion Selective Electrode (ISE); millimol/milliliter

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

At the end of hospitalization

Method of measurement

Number of days

2

Description

Total cost of medicine used

Timepoint

At the end of drug therapy

Method of measurement

Total cost of medicine in Rials

Intervention groups

1

Description

Intervention group: Intravenous infusion of 500 ml Mannitol 20% at the same time with 500 ml Glucose 5% using y-site over 4 hours daily or twice a day a (based on clinical responses). Intravenous solutions are the products of Shahid Ghazi (Tabriz- Iran) factories.

Category

Other

2

Description

Control group: Intravenous infusion of 100g Human Albumin (5 vials of 20% Albumin) over 4 hours, repeating every 4 to 12 hours (based on clinical responses). Albumin vials are the product of OCTAPHARMA AG- Switzerland.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarem Specialized Hospital

Full name of responsible person

AboTaleb Saremi

Street address

Basij Sq., Phase 3, Ekbatan Town

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Email

saremiat@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sarem Fertility and Infertility Research Center (SAFIR)

Full name of responsible person

AboTaleb Saremi

Street address

Sarem Fertility and Infertility Research Center, phase3, Ekbatan town

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Arashpooladi@saremcrc.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sarem Fertility and Infertility Research Center (SAFIR)

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

sarem Fertility and Infertility Research Center (SAFIR)

Full name of responsible person

Maryam Namdar Khanzadeh

Position

Head of pharmaceutical Care Department

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Sarem fertility and Infertility Research Center (SAFIR),
Sarem women's hospital, shahrak-e-Ekbatan, phase 3,
Tehran, Iran.

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Email

dr.m_namdar@saremcrc.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sarem Fertility and Infertility Research Center (SAFIR)

Full name of responsible person

AboTaleb Saremi

Position

Chairman of Sarem women's hospital and Sarem
Fertility and Infertility Research Center (SAFIR)

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

sarem Fertility and Infertility Research Center (SAFIR)

Full name of responsible person

Maryam Namdar Khanzadeh

Position

Head of pharmaceutical Care Department

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Sarem Fertility and Infertility Research Center
(SAFIR), Sarem women's hospital, shahrak-e-Ekbatan,
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Email

dr.m_namdar@saremcrc.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information on the main outcomes of the study is
available for sharing.

When the data will become available and for how long

The beginning of the access period is 6 months after the
publication of the results of the study.

To whom data/document is available

Official assessors of the research field of the Iran
University of Medical Sciences (IUMS)

Under which criteria data/document could be used

- To verify the accuracy of the analysis of the study -
Modeling for future studies - Use for future meta
analyses

From where data/document is obtainable

Sarem Fertility and Infertility Research Center (SAFIR)

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

The official application to "Iran University of Medicalscience (IUMS)" will be communicated to the "Sarem Fertility and Infertility Research Center (SAFIR)"

after being approved by the competent authorities. After receiving the request, SAFIR will contact the applicant within 10 days to answer the questions.

Comments