Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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 htper 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
۱۴۴۹۶۱۴۵۳۵
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 ti 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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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 Khanzedeh

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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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

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

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Email
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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 analyzes

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