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The usefulness of assessing markers of severity among women with ovarian hyperstimulation syndrome

Submission date
12/05/2020

Recruitment status
No longer recruiting

Registration date
19/05/2020

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Ovarian hyperstimulation syndrome (OHSS) is the most severe and potentially life-threatening iatrogenic complication associated with assisted reproduction. Its pathophysiology and clinic are similar to the intra-abdominal hypertension syndrome being ovarian enlargement and ascites progression the main factors for the growth of intra-abdominal pressure. The aim of the present study is the assessment of the usefulness of markers of severity among women with OHSS.

Who can participate?
The study includes women admitted to the hospital with clinical evidence of OHSS were asked to take part in the study. All women had primary / secondary infertility and were in an in vitro fertilization program (IVF).

What does the study involve?
Seventy-six women with varying degrees of severity of OHSS were recruited in a single centre. All women underwent clinical and laboratory examination, and ultrasound measurement of the ovarian size and free abdominal fluid. Ovarian volumes were assessed using the prolate ellipsoid formula and ascites index was recorded. Intra-abdominal pressure was measured using an intravesical Foley Manometer catheter. Ovarian volumes, ascites index and intra-abdominal pressure were stratified according to the clinical severity of OHSS.

What are the possible benefits and risks of participating?
Possible benefits for patients are to clarify the stage of OHSS and the strategy for further treatment. The study carries no risks for patients; all research methods are non-invasive.

Where is the study run from?
City clinical hospital No.1 named after Yu.Ya. Gordeev, Saratov, Russian Federation.

When is the study starting and how long is it expected to run for?
January 2015 to December 2019

Who is funding the study?
Government of the Russian Federation

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Role of intra-abdominal hypertension in the development and outcome of ovarian hyperstimulation syndrome

Acronym
IAHOHSS

Study objectives

The development of moderate, severe, and critical OHSS is accompanied by an increase in intra-abdominal volume and intra-abdominal hypertension. Assessing the dynamics of ovarian volume, ascites and intra-abdominal pressure could be a useful tool in defining the severity of OHSS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/03/2018, Ethics Committee of the Saratov State Medical University named after V. I. Razumovsky, Saratov, Russian Federation (+7 9272777606). Naumova-L@yandex.ru P.№7

Study design
Prospective single-center observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Ovarian hyperstimulation syndrome (OHSS)

Interventions
Seventy-six women with varying degrees of severity of OHSS were recruited in a single centre. All women underwent clinical and laboratory examination, and ultrasound measurement of the ovarian size and free abdominal fluid. Ovarian volumes were assessed using the prolate ellipsoid formula and ascites index was recorded. Intra-abdominal pressure was measured using an intravesical Foley Manometer catheter. Ovarian volumes, ascites index and intra-abdominal pressure were stratified according to the clinical severity of OHSS.

Intervention Type
Other

Primary outcome measure
Confirmed ovarian hyperstimulation syndrome measured using ultrasound, routine laboratory tests, and clinical examination including height, body weight, abdominal circumference, dehydration assessment, edema, heart rate, respiratory rate, blood pressure and diuresis at time of observation

Secondary outcome measures

1. Ovarian volume measured using the prolate ellipsoid formula at time of observation
2. Ascites index measured using ultrasound by summing the sizes of the free fluid (in mm) in the largest free pockets of the external abdominal quadrants including inguinal regions and the liver and spleen areas at time of observation
3. Intra-abdominal pressure measured using an intravesical Foley Manometer catheter at time of observation

Overall study start date
01/01/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
All women admitted to the hospital with clinical evidence of OHSS were asked to take part in the study

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
76

Total final enrolment
76

Key exclusion criteria
Women who voluntarily refused to participate in the study

Date of first enrolment
10/06/2018

Date of final enrolment
20/09/2019

Locations

Countries of recruitment
Russian Federation

Study participating centre
City Clinical Hospital №1 named after Yu.Ya. Gordeev
st. Holzunova 19
Saratov
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Sponsor information

Organisation
Federal State Budgetary Institution “Center for the Development of Education and International Activities (“Inter-education”)

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Federal State Budgetary Institution “Center for the Development of Education and International Activities (“Inter-education”).

Results and Publications

Publication and dissemination plan
Results will be published in a peer-reviewed journal.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			22/02/2022	No	No
Dataset		03/11/2021	14/06/2023	No	No
Results article		10/05/2022	14/06/2023	Yes	No