Stress managment and in vitro fertilization outcomes

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Main Information

Primary registry identifying number
LBCTR2019101289

Protocol number
OBS-2018-002

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
This is a retrospective registration since, honestly,at the beginning of this trial and while preparing the documents requested by the IRB for the ethical apprval, we were never informed that the trial should be registered.

Date of registration in national regulatory agency

Primary sponsor
Azoury IVF clinic and Al-Hadi laboratory and medical center

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
04/11/2019

Date of registration in national regulatory agency

Public title
Stress managment and in vitro fertilization outcomes

Acronym
SMP

Scientific title
The impact of stress managment during in vitro fertilization on embryo development and mental health

Acronym
SMP

Brief summary of the study: English

STUDY QUESTION
Does a stress management program during infertility treatment impact the cortisol level in the follicular fluid and subsequently embryo development?
WHAT IS KNOWN ALREADY
The process of infertility treatment requires at least one month of preparation. During this period, the women undergo ovarian stimulation using gonadotropins followed by trans-vaginal oocyte aspiration under local anesthesia. Several studies showed that stress and anxiety are common psychological conditions during infertility treatment procedures (Cesta, Johansson et al. 2017). The biological responses to stress involve the regulation of the adrenal glands activity (McEwen 2016). The cortisol, a glucocorticoid hormone secreted by the adrenal gland cortex, plays an important role in the local regulation of human ovarian follicles. For instance, it was demonstrated that cortisol may trigger apoptosis of ovarian cells (Yuan, Han et al. 2016), may regulate the secretion of insulin-like growth factors (IGF-2,4,5) in the granulosa cells (Spicer and Chamberlain 1998), and may influence the oocyte lipid metabolism (Simerman, Hill et al. 2015). However, the impact of stress management on oocyte quality, embryo development, and in vitro fertilization (IVF) outcome did not A randomized controlled trial (RCT) will be conducted at Azoury IVF clinic, Mount-Lebanon hospital. It will be performed on couples undergoing IVF with intra- reach a firm consensus.
STUDY DESIGN, SIZE, DURATION
cytoplasmic sperm injection cycles. These IVF cycles will be conducted by Dr. Joseph Azoury (MD). At the first day of ovarian stimulation using the antagonist protocol (Gonal-f, Cetrotide, and Ovitrelle), in-person interviews will be conducted with infertile couples to answer a questionnaire about their medical history. In parallel, perceived stress level will be evaluated using the Perceived Stress Scale (PSS). Subsequently, the infertile couples will be randomly divided into two groups (n=50 couples each). One of the groups will be subjected to a stress management program (SMP) during infertility treatment. The stress management program will be under the supervision of Dr.Georges Raad (PhD), Miss Judy Tanios (MSc), and Mrs. Simone Kerbaj (MSc). At the day of egg retrieval, psychological stress of the patients, in both groups, will be assessed using the PSS.
PARTICIPANTS/MATERIALS, SETTING, METHODS
After egg retrieval, the collected follicular fluid will be centrifuged. The supernatant will be used for cortisol measurements and the granulosa cells in the pellet will be cryopreserved for further molecular investigations at Al Hadi medical and laboratory center. Moreover, oocyte quality and embryo morphokinetics will be analysed according to international guidelines through time-lapse microscopy (Embryoscope) using the Embryoviewer software.
COMPETING INTEREST(S)
No conflict of interest.

Brief summary of the study: Arabic

المسألة
هل يؤثر برنامج إدارة الإجهاد أثناء علاج العقم على مستوى الكورتيزول في السائل المسامي ومن ثم تطور الجنين؟

الخلفية العلمية
تتطلب عملية علاج العقم شهرًا واحدًا على الأقل من التحضير. خلال هذه الفترة، تخضع المرأة لتحفيز المبيض باستخدامهرمونات موجهة للغدد التناسلية تليها سحب البويضة عبر المهبل تحت التخدير الموضعي. أظهرت العديد من الدراسات أن التوتر والقلق من الحالات النفسية الشائعة أثناء إجراءات علاج العقم. تتضمن الاستجابات البيولوجية للتوتر تنظيم نشاط الغدد الكظرية. يلعب الكورتيزول، وهو هرمون غلوكورتيكويد يفرز من قشرة الغدة الكظرية، دورًا مهمًا في التنظيم المحلي للمبيض البشري. على سبيل المثال، تم إثبات أن الكورتيزول قد يؤدي إلى موت الخلايا (Granulosa) ، وقد يؤثر على استقلاب الدهون في البويضة. ومع ذلك، فإن تأثير إدارة الإجهاد على جودة البويضة، وتطور الأجنة ، والإخصاب في المختبر (IVF) النتيجة لم تصل إلى توافق في الآراء.

تصميم الدراسة ، الحجم ، المدة
سيتم إجراءالبحث في عيادة عازوري لأطفال الأنابيب ، مستشفى جبل لبنان. سيتم تنفيذه على الأزواج الذين يخضعون لعمليات التلقيح الصناعي مع دورات حقن الحيوانات المنوية داخل السيتوبلازم. سيتم إجراء دورات التلقيح الصناعي هذه بواسطة الدكتور جوزيف عازوري في اليوم الأول من تنشيط المبيض
. سيتم إجراء مقابلات شخصية مع الأزواج المصابين بالعقم للإجابة على استبيان حول تاريخهم الطبي. في موازاة ذلك ، سيتم تقييم مستوى التوتر المدرك باستخدام مقياس الإجهاد المدرك. بعد ذلك ، سيتم تقسيم الأزواج المصابين بالعقم بشكل عشوائي إلى مجموعتين .ستخضع إحدى المجموعات لبرنامج إدارة الإجهاد أثناء علاج العقم. سيكون برنامج إدارة الإجهاد تحت إشراف الدكتور جورج رعد (دكتوراه) ، والسيدة جودي ، تانيوس (ماجستير) ، والسيدة سيمون كيرباج (ماجستير). في يوم استرجاع البيض ، سيتم تقييم الضغط النفسي للمرضى ، في كلتا المجموعتين باستخدام.

المشاركون / المواد ، والإعداد ، والطرق

بعد استرجاع البويضة، سيتم جمع السائل المسامي. سيتم استخدام المادة الطافية في قياسات الكورتيزول وسيتم حفظ خلايا الحبيبية في الحبيبات لمزيد من التحقيقات الجزيئيةفي مركز الهادي الطبي. علاوة على ذلك، سيتم تحليل جودة البويضة ومورفونيات الجنين وفقًا للإرشادات الدولية من خلال الفحص المجهري الفاصل.

Health conditions/problem studied: Specify

Psychological stress during infertility treatment (specifically IVF)

Interventions: Specify

A randomized controlled trial (RCT) will be conducted at Azoury IVF clinic, Mount-Lebanon hospital. It will be performed on couples undergoing IVF with intra-cytoplasmic sperm injection cycles. These IVF cycles will be conducted by Dr. Joseph Azoury (MD). At the first day of ovarian stimulation using the antagonist protocol (Gonal-f, Cetrotide, and Ovitrelle), in-person interviews will be conducted with infertile couples to answer a questionnaire about their medical history. In parallel, perceived stress level will be evaluated using the Perceived Stress Scale (PSS). Subsequently, the infertile couples will be randomly divided into two groups. One of the groups will be subjected to a stress management program (SMP) during infertility treatment. The stress management program will be under the supervision of Dr.Georges Raad (PhD), Miss Judy Tanios (MSc), and Mrs. Simone Kerbaj (MSc). At the day of egg retrieval, psychological stress of the patients, in both groups, will be assessed using the PSS.

Key inclusion and exclusion criteria: Inclusion criteria

women <38 years old
couples undergoing intracytoplasmic sperm injection
men with ejaculated sperm
couples without psychiatric disorders/treatment

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

21

Key inclusion and exclusion criteria: Age maximum

38

Key inclusion and exclusion criteria: Exclusion criteria

women >39 years old
men with testicular biopsy
men/women under psychiatric treatment
couples with severe male factor

Type of study

Interventional

Type of intervention

Educations programs

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation
Randomized controlled trial

Study design: Masking
Blinded (masking used)

Study design: Control
Active

Study phase
0 (explanatory trials)

Study design: Purpose
Supportive care

Study design: Specify purpose
N/A

Study design: Assignment
Parallel

Study design: Specify assignment
N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class
Not applicable

Therapeutic indication
To reduce IVF-associated stress

Therapeutic benefit
Improving mental health and pregnancy outcomes in infertile patients

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention
Samples without DNA

Biospecimen description

Leftover follicular fluid: for endocrine measurments
Leftover Granulosa cells: for cytologic analysis

Target sample size
60

Actual enrollment target size
58

Date of first enrollment: Type
Actual

Date of first enrollment: Date
01/09/2018

Date of study closure: Type
Actual

Date of study closure: Date
15/08/2019

Recruitment status
Complete

Recruitment status: Specify

Date of completion
31/10/2019

IPD sharing statement plan
No

IPD sharing statement description
N/A

Additional data URL

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Mount-Lebanon Hospital	OBS-2018-002

Sources of Monetary or Material Support

Name
Azoury IVF clinic, Mount Lebanon Hospital

Secondary Sponsors

Name
Al Hadi medical and laboratory center

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Chadi Fakih	Haret Hreik	Lebanon	009617675 5442	drchsadifakih@yahoo.fr	head of Al hadi center
Scientific	Georges Raad	Haret Hreik	Lebanon	009613953 654	georges.raad@live.com	research associate

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Mount Lebanon Hospital	Joseph Azouri	Gynecology and Obstetrics	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Mount Lebanon Hospital	16/08/2018	Marie Merheb	marie.merheb@mlh.com.lb	+961-5-957 000

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
infertility	In vitro fertilization (Z31.2)	stress, pregnancy, IVF

Interventions

Intervention	Description	Keyword
patient education	RCT	Perceived stress, Ovarian stimulation, follicular fluid, egg quality, embryo morphokinetics

Primary Outcomes

Name	Time Points	Measure
Hormonal profile	in the follicular fluid at the time of oocyte aspiration	hormones measurments RIA

Key Secondary Outcomes

Name	Time Points	Measure
mental health	before and at the end of the treatment	percieved stress scale

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files