



Stress management 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 approval, 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 management and in vitro fertilization outcomes

Acronym

SMP

Scientific title

The impact of stress management 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 المسمامي ومن ثم تطور الجنين؟

الخلفية العلمية

تتطلب عملية علاج العقم شهراً واحداً على الأقل من التحضير. خلال هذه الفترة، تخضع المرأة لتحفيز المبيض باستخدام هرمونات 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 الغدة الكظرية. يلعب الكورتيزول، وهو هرمون غلوكورتيكويد يفرز من قشرة الغدة الكظرية، دوراً مهماً في التنظيم المحلي للمبيض البشري. على سبيل المثال، تم إثبات أن الكورتيزول قد يؤدي إلى موت الخلايا، وقد يؤثر على استقلاب الدهون في البويضة. ومع ذلك، فإن تأثير إدارة الإجهاد على جودة البويضة، وتطور الأجنة، (Granulosa)، النتيجة لم تصل إلى توافق في الآراء (IVF) والإخصاب في المختبر.

تصميم الدراسة، الحجم، المدة

سيتم إجراء البحث في عيادة عازوري لأطفال الأنابيب، مستشفى جبل لبنان. سيتم تنفيذ 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.

المشاركين / المواد، والإعداد، والطرق

بعد استرجاع البويضة، سيتم جمع السائل المسمامي. سيتم استخدام المادة الطاقية في قياسات الكورتيزول وسيتم حفظ خلايا الحبيبية في الحبيبات لمزيد من التحقيقات الجزيئية في مركز الهادي الطبي. علاوة على ذلك، سيتم تحليل جودة البويضة ومورفونيات الجنين وفقاً للإرشادات الدولية من خلال الفحص المجهرى 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: Control

Active

Study design: Purpose

Supportive care

Study design: Assignment

Parallel

IMP has market authorization**Name of IMP****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: Specify model

N/A

Time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration**Number of groups/cohorts****Biospecimen retention**

Samples without DNA

Study design: Masking

Blinded (masking used)

Study phase

0 (explanatory trials)

Study design: Specify purpose

N/A

Study design: Specify assignment

N/A

IMP has market authorization: Specify**Year of authorization****Month of authorization****Study model: Explain model**

N/A

Time perspective: Explain time perspective

N/A

Target follow-up duration: Unit**Biospecimen description**



Leftover follicular fluid: for endocrine measurements
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 Fakhri	Haret Hreik	Lebanon	0096176755442	drchsadifakhri@yahoo.fr	head of Al hadi center
Scientific	Georges Raad	Haret Hreik	Lebanon	009613953654	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 measurements 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