

Dietary Omega 3 supplementation and its effect on oocyte competence and follicular fluid in female patients undergoing IVF: a single prospective interventional study

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Primary registry identifying number

LBCTR2021044539

MOH registration number

Study registered at the country of origin

Type of registration

Prospective

Date of registration in national regulatory

07/08/2020

Primary sponsor

Al Hadi IVF Center

Date of registration in primary registry

13/10/2021

Public title

Dietary Omega 3 supplementation and its effect on oocyte competence and follicular fluid in female patients undergoing IVF: a single prospective interventional study

Scientific title

Dietary Omega 3 supplementation and its effect on oocyte competence and follicular fluid in female patients undergoing IVF: a single prospective interventional study

Brief summary of the study: English

We are doing a study about the effect of omega 3 supplementation on ICSI outcomes. There is increasing evidence that omega 3 supplementation prior to ICSI increase the success rate without direct evidence. The project will involve whether taking omega 3 supplementation (known as Vita DHA Materna by U.G.A) or not, and answering a questionnaire about your medical background.

Brief summary of the study: Arabic

يزيد من نسبة نجاح عملية قبل عملية أطفال الأنابيب هناك أدلة متزايدة على أن إستخدام الأوميغا 3نحن نقوم بدراسة بشأن إعطاء الأوميغا أطفال الأنابيب دون وجود دراسات ذات مستوى علمي مرتفع تكد على هذه النظرية. سيشمل المشروع إما أخذ حبوب تحتوي على الأوميغا و الأجابة على بعض الأسئلة في بداية العلاج و المتابعة خلال فترة العلاج

Health conditions/problem studied: Specify

ICSI outcome follicular fluid composition epigenetic modifications oocyte competence Oxidative stress

Protocol number

OBS-2019-004

Study registered at the country of origin: Specify

Type of registration: Justify

N/A

Primary sponsor: Country of origin

Lebanon

Date of registration in national regulatory agency

07/08/2020

Acronym

Acronym



Interventions: Specify

Group: control

Group: 200mg DHA + 50mg EPA Group: 400mg DHA + 100mg EPA

Randomly divided

Key inclusion and exclusion criteria: Inclusion criteria

< 3 IVF attempts Normal uterine activity

Key inclusion and exclusion criteria: Gender

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age maximum

Female

Key inclusion and exclusion criteria: Age minimum

Key inclusion and exclusion criteria: Exclusion criteria

The cycles involving percutaneous epididymal sperm aspiration must be excluded.

Type of study

Interventional

Type of intervention

Dietary interventions

Trial scope

Dose-response

Study design: Allocation Randomized controlled trial

Study design: Control

Placebo

Study design: Purpose

Supportive care

Study design: Assignment

Parallel

IMP has market authorization

Type of intervention: Specify type

N/A

Trial scope: Specify scope

N/A

Study design: Masking Blinded (masking used)

Study phase

0 (explanatory trials)

Study design: Specify purpose

Study design: Specify assignment

IMP has market authorization: Specify

Year of authorization Month of authorization

Type of IMP

Name of IMP

Pharmaceutical class

EPA and DHA

Therapeutic indication

oxidative stress

Therapeutic benefit

oxidative stress reduction enhance embryo quality

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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

Target sample size

250

Date of first enrollment: Type

Anticipated

Date of study closure: Type

Anticipated

Recruitment status

Recruiting

Date of completion

IPD sharing statement plan

Yes

Study model: Explain model

N/A

Time perspective: Explain time perspective

N/A

Target follow-up duration: Unit

Biospecimen description

Follicular Fluid biochemistry

Actual enrollment target size

Date of first enrollment: Date

01/07/2020

Date of study closure: Date

01/05/2021

Recruitment status: Specify

IPD sharing statement description

All data will be disclosed and confidentially saved on excel sheets

Additional data URL

Admin comments



Trial status

Approved

Secondary Identifying Numbers		
Full name of issuing authority	Secondary identifying number	
Mount Lebanon Hospital	05957000	

Sources of Monetary or Material Support

Name

Al Hadi Laboratory and Medical Center

Secondary Sponsors

Name

NA

Contact for Public/Scientific Queries						
Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Chadi Fakih	Haret Hreik	Lebanon	03755442	drchadifakih@ya hoo.fr	Al Hadi Laboratory and Medical Center
Scientific	Chadi Fakih	Haret Hreik	Lebanon	03755442	drchadifakih@ya hoo.fr	Al Hadi Laboratory and Medical Center

Centers/Hospitals Involved in the Study					
Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval		
Al Hadi Laboratory and Medical Center	Chadi Fakih	Doctor	Approved		
Al Hadi Laboratory and Medical Center	Ranine Zahwe	Research and Medical Assistant	Approved		



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Ethics Review					
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone	
Mount Lebanon Hospital	01/07/2020	Dr. Marie Merheb	marie.merheb@mlh.com.lb	05957000	

Countries of Recruitment Name Lebanon

Health Conditions or Problems Studied			
Condition	Code	Keyword	
In vitro fertilization	In vitro fertilization (Z31.2)	IVF	

Interventions			
Intervention	Description	Keyword	
Pharmaceutical	Dose	EPA , DHA	

Primary Outcomes				
Name	Time Points	Measure		
Oocyte Competence	after 3 months	Fertilization + embryo quality		

Key Secondary Outcomes				
Name	Time Points	Measure		
Pregnancy Rate	after 1 month	hCG test		
Live Birth Rate	after 9 months of last recruitment	Alive or not		



Lebanon Clinical Trials Registry

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				