



# 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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## Main Information

**Primary registry identifying number**

LBCTR2021044539

**Protocol number**

OBS-2019-004

**MOH registration number**

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Prospective

**Type of registration: Justify**

N/A

**Date of registration in national regulatory agency**

07/08/2020

**Primary sponsor**

Al Hadi IVF Center

**Primary sponsor: Country of origin**

Lebanon

**Date of registration in primary registry**

13/10/2021

**Date of registration in national regulatory agency**

07/08/2020

**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

**Acronym**

**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

**Acronym**

**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 3 قبل عملية أطفال الأنابيب. هناك أدلة متزايدة على أن استخدام الأوميغا 3 نحن نقوم بدراسة بشأن إعطاء الأوميغا 3 أطفال الأنابيب دون وجود دراسات ذات مستوى علمي مرتفع تكفي على هذه النظرية. سيتمثل المشروع إما أخذ حبوب تحتوي على الأوميغا 3 والأجابة 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

**Interventions: Specify**

Group: control  
Group: 200mg DHA + 50mg EPA  
Group: 400mg DHA + 100mg EPA  
Randomly divided

**Key inclusion and exclusion criteria: Inclusion criteria**

18 < age < 45  
< 3 IVF attempts  
Normal uterine activity

**Key inclusion and exclusion criteria: Gender**

Female

**Key inclusion and exclusion criteria: Specify gender****Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

45

**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

**Type of intervention: Specify type**

N/A

**Trial scope**

Dose-response

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Blinded (masking used)

**Study design: Control**

Placebo

**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**

EPA and DHA

**Therapeutic indication**

oxidative stress

**Therapeutic benefit**

oxidative stress reduction  
enhance embryo quality



**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**

Follicular Fluid  
biochemistry

**Target sample size**

250

**Actual enrollment target size**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

01/07/2020

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

01/05/2021

**Recruitment status**

Recruiting

**Recruitment status: Specify**

**Date of completion**

**IPD sharing statement plan**

Yes

**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 Fakhri	Haret Hreik	Lebanon	03755442	drchadifakhri@yahoo.fr	Al Hadi Laboratory and Medical Center
Scientific	Chadi Fakhri	Haret Hreik	Lebanon	03755442	drchadifakhri@yahoo.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 Fakhri	Doctor	Approved
Al Hadi Laboratory and Medical Center	Ranine Zahwe	Research and Medical Assistant	Approved



## 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



## 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**