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

03/04/2025 10:47:05

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

نحن نقوم بدراسة بشأن إعطاء الأوميغا 3 قبل عملية أطفال الأنابيب.هناك أدلة متزايدة على أن إستخدام الأوميغا 3 يزيد من نسبة نجاح عملية 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

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 Fakih	Haret Hreik	Lebanon	03755442	drchadifakih@yahoo.fr	Al Hadi Laboratory and Medical Center
Scientific	Chadi Fakih	Haret Hreik	Lebanon	03755442	drchadifakih@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 Fakih	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