The effect of intrauterine administration of human gonadotropin (HCG) on implantation and pregnancy rates in IUI (intrauterine insemination cycles) cycles: a randomized prospective study

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Main Information

Primary registry identifying number
LBCTR2021034751

Protocol number
OBS-2019-005

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
01/07/2020

Primary sponsor
Al Hadi Laboratory and Medical Center

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
03/04/2021

Date of registration in national regulatory agency
01/07/2020

Public title
The effect of intrauterine administration of human gonadotropin (HCG) on implantation and pregnancy rates in IUI (intrauterine insemination cycles) cycles: a randomized prospective study

Acronym

Scientific title
The effect of intrauterine administration of human gonadotropin (HCG) on implantation and pregnancy rates in IUI (intrauterine insemination cycles) cycles: a randomized prospective study

Acronym

Brief summary of the study: English
We are doing a study about the effect of administrating HCG hormone in the uterine cavity along with the semen sample during intrauterine insemination to study if there is any modification in live birth rate. HCG has proved its efficacy in IVF procedure but not yet studied in intra uterine insemination.

Brief summary of the study: Arabic
نحن نقوم بمشروع بشأن إضافة هرمون ال HCG الى السائل المنوي قبل حقنه داخل الرحم. تشير الدراسات أن إستخدام هرمون ال HCG يزيد من نسب إنغراس الجنين داخل الرحم خلال عمليات أطفال الأنابيب. و لكن لا يوجد دراسات تشير الى أهمية هذا الهرمون خلال عملية الحقن السائل المنوي داخل الرحم.

Health conditions/problem studied: Specify
The study involves patients suffering from infertility and willing to start an IUI procedure.

Interventions: Specify
The project will involve whether administrating different doses of HCG (known as Choriomon HCG 5000 - IBSA) along with the semen sample in the uterus or not during intrauterine insemination.

Key inclusion and exclusion criteria: Inclusion criteria

We are inviting 210 patients attending the Al Hadi IVF Center to start the infertility treatment for IUI, in which the age of the female partner is less than 38 years old.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

38

Key inclusion and exclusion criteria: Exclusion criteria

sperm count less than 1 million and progressive motility less than 30%
Advanced maternal age
bilateral tubal stenosis

Type of study

Interventional

Type of intervention

Pharmaceutical

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

2

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Lebanon and worldwide

Name of IMP

Choriomon 5000

Year of authorization

Month of authorization

Type of IMP

Others

Pharmaceutical class

Hormone

Therapeutic indication

Human chorionic gonadotropin (HCG) is a hormone that supports the normal development of an egg in a woman's ovary, and stimulates the release of the egg during ovulation.

Therapeutic benefit

HCG is used to cause ovulation and to treat infertility in women, and to increase sperm count in men.

Study model

N/A

Study model: Explain model

Study model: Specify model

N/A

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
None retained

Biospecimen description
Semen sample

Target sample size
200

Actual enrollment target size

Date of first enrollment: Type
Actual

Date of first enrollment: Date
01/08/2020

Date of study closure: Type
Actual

Date of study closure: Date
01/04/2021

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
Not Available

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 Center	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	HCG

Primary Outcomes

Name	Time Points	Measure
Live Birth Rate	after 9 months of last recruitment	Alive or not

Key Secondary Outcomes

Name	Time Points	Measure
Pregnancy Rate	after 3 months of last recruitment	gestational sac

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