



# 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

يزيد HCG الى السائل المنوي قبل حقنه داخل الرحم. تشير الدراسات أن استخدام هرمون الـ HCG نحن نقوم بمشروع بشأن إضافة هرمون الـ HCG الى السائل المنوي داخل الرحم خلال عمليات أطفال الأنابيب. و لكن لا يوجد دراسات تشير الى أهمية هذا الهرمون خلال عملية الحقن من نسب إنغراس الجنين داخل الرحم خلال عمليات أطفال الأنابيب.

### 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
<b>Time perspective</b> N/A	<b>Time perspective: Explain time perspective</b> N/A
<b>Time perspective: Specify perspective</b> N/A	
<b>Target follow-up duration</b>	<b>Target follow-up duration: Unit</b>
<b>Number of groups/cohorts</b>	
<b>Biospecimen retention</b> None retained	<b>Biospecimen description</b> Semen sample
<b>Target sample size</b> 200	<b>Actual enrollment target size</b>
<b>Date of first enrollment: Type</b> Actual	<b>Date of first enrollment: Date</b> 01/08/2020
<b>Date of study closure: Type</b> Actual	<b>Date of study closure: Date</b> 01/04/2021
<b>Recruitment status</b> Recruiting	<b>Recruitment status: Specify</b>
<b>Date of completion</b>	
<b>IPD sharing statement plan</b> Yes	<b>IPD sharing statement description</b> All data will be disclosed and confidentially saved on excel sheets
<b>Additional data URL</b>	
<b>Admin comments</b>	

**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