

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Estradiol valerate pretreatment in short protocol GnRH-agonist cycles versus combined pretreatment with oral contraceptive pills in long protocol GnRH-agonist cycles: a randomised controlled trial

Protocol summary

Summary

The aim of our study was to compare the differences in pregnancy rates (PRs), implantation rates and miscarriage rates between a short agonist protocol with estradiol priming and a long protocol with combined OC. The inclusion criteria were as follows: women younger than 40 years old; an AMH level greater than 0.6 ng/mL; a body mass index between 18 and 29 kg/m²; and undergoing a first or second treatment cycle of IVF with intracytoplasmic sperm injection (ICSI). The exclusion criteria were endometriosis and preimplantation diagnosis cycles. After providing written consent, the 298 participants were randomly divided into one of the two study groups (154 patients who were treated with long GnRH agonist with combined OC pretreatment and 144 who were treated with short GnRH agonist with estradiol pretreatment). The doctors performing the oocyte retrieval procedure and the embryologists involved were blind to the treatment groups. Our primary outcome measure was clinical pregnancy rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020418202N4**

Registration date: **2015-02-27, 1393/12/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-27, 1393/12/08

Registrant information

Name

Judyta Zabielska

Name of organization / entity

Invicta Sp.z o.o.

Country

Poland

Phone

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Recruitment status

Recruitment complete

Funding source

Invicta sp.z o.o.

Expected recruitment start date

2013-07-01, 1392/04/10

Expected recruitment end date

2014-01-01, 1392/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Estradiol valerate pretreatment in short protocol GnRH-agonist cycles versus combined pretreatment with oral contraceptive pills in long protocol GnRH-agonist cycles: a randomised controlled trial

Public title

Comparison of short agonist vs long agonist stimulation protocol and different pretreatment s in women undergoing in vitro fertilization.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: women younger than 40 years old; an AMH level greater than 0.6 ng/mL; a body mass index

between 18 and 29 kg/m²; first or second treatment cycle of IVF with intracytoplasmic sperm injection (ICSI).
Exclusion: endometriosis; preimplantation diagnosis cycles

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **298**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Bioethics Committee in Gdansk

Street address

ul. Sniadeckich 33

City

Gdansk

Postal code

80-204

Approval date

2013-03-26, 1392/01/06

Ethics committee reference number

Kb 9/13

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes**1****Description**

pregnancy rate

Timepoint

on 6 weeks and 1-3 days

Method of measurement

clinical pregnancy (as ultrasound fetal heartbeat detection)

Secondary outcomes**1****Description**

implantation rate

Timepoint

7 days after transfer

Method of measurement

blood serum beta-HCG concentration

Intervention groups**1****Description**

Estradiol valerate pretreatment (2mg oral estradiol twice daily from the 20th day of cycle until 1-4th day of new cycle. in short protocol GnRH-agonist cycles (150-225 IU/day hMG continued with a daily dose of triptorelin 0.1 mg until the hCG injection - Chpragon 5000 administered 36 hours before retrieval.)

Category

Treatment - Drugs

2**Description**

Combined pretreatment with oral contraceptive pills (Ovulostan from 2nd to 4th day of cycle) in long protocol GnRH-agonist cycles (0.1 mg Triptorelin beginning on the 14th day of the cycle, every 2 days, for two weeks, 150-225 IU/day hMG continued with a daily dose of triptorelin 0.1 mg until the hCG injection - Chpragon 5000 administered 36 hours before retrieval.)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Invicta Fertility and Reproduction Centre

Full name of responsible person

Judytra Zabielska

Street address**City**

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Invicta Fertility and Reproduction Centre sp.z o.o.

Full name of responsible person

Judyta Zabielska

Street address

Trzy lipy 3

City

Gdansk

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Invicta Fertility and Reproduction Centre sp.z o.o.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Invicta Fertility and Reproduction Centre sp.z o.o.

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

