

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The impact of next generation sequencing (NGS) preimplantation genetic diagnostics (PGD) on pregnancy rate of frozen blastocyst embryo transfer.

Protocol summary

Summary

Objectives: To determine pregnancy rate after comprehensive chromosome screening (CCS) using PGD NGS in frozen embryo transfer cycles after blastocyst's trophoectoderm biopsy. **Design:** Prospective study. **Setting:** A private centers for reproductive medicine. **Material and methods:** 40 patients who will decide to undergo PGD on 24 chromosomes on blastocystes with vitrification and frozen embryo transfer will be included in the study as a investigated group. A control group was adjusted according to anti-Müllerian hormone level (AMH) and antral follicle count (AFC). This group included 34 cases in whom a fresh cycle transfer was postponed for several reasons: progesterone > 2.0 ng / ml on the day of hCG administration (n = 16); endometrial thickness <6 mm on the day of hCG administration (n = 9); and a risk of ovarian hyperstimulation syndrome (OHSS) (n = 9) with qualification for FET cycle; this group involved frozen blastocysts without PGD transfer. **Intervention(s):** Choice of the embryos for transfer based on the PGD NGS results. **Main Outcome Measure(s):** Clinical pregnancy rate (PR) per embryo transfer will be our primary outcome. Secondary outcome will be the implantation rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062318202N1**
Registration date: **2014-07-10, 1393/04/19**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-10, 1393/04/19

Registrant information

Name

Judyta Zabielska

Name of organization / entity

Invicta Sp.z o.o.

Country

Poland

Phone

0048 516 829 691

Email address

zabielska@gumed.edu.pl

Recruitment status

Recruitment complete

Funding source

Funded by Invicta s.z o.o.

Expected recruitment start date

2014-08-01, 1393/05/10

Expected recruitment end date

2014-09-01, 1393/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of next generation sequencing (NGS) preimplantation genetic diagnostics (PGD) on pregnancy rate of frozen blastocyst embryo transfer.

Public title

The impact of next generation sequencing (NGS) preimplantation genetic diagnostics (PGD) on pregnancy rate of frozen blastocyst embryo transfer.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion: 1. Patients undergoing assisted reproductive treatment with intracytoplasmic sperm injection and frozen blastocyst embryo transfer in Invicta Fertility and Reproductive Centre s. z o.o. in time frame from 08.2014 to 09.2014 Exclusion: 1. Blastocysts in stages 2CC, 3CC, 4CC, and 5CC did not qualify for biopsy. 2. Patients in whom no normal embryo was available

Age

From **33 years** old to **42 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Komisja Bioetyczna przy Okręgowej Izbie Lekarskiej

Street address

ul. Śniadeckich 33

City

Gdańsk

Postal code

80-214

Approval date

2014-05-20, 1393/02/30

Ethics committee reference number

KB 12/14

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 day after transfer

Method of measurement

blood serum beta-HCG concentration

Intervention groups

1

Description

Next Generation Sequencing Preimplantation Genetic Diagnosis embryo selection

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Invicta Fertility and Reproductive Centre

Full name of responsible person

Judyta Zabielska

Street address

GPNT ul. Trzy lipy 3

City

Gdańsk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Invicta s.z o.o.

Full name of responsible person

Jolanta Jabłońska

Street address

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City

Gdańsk

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Invicta s.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 Gdańsk
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Person responsible for updating data

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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
Data Dictionary
empty