

# 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 blastocysts 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

ul. Trzy lipy 3

##### 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  
**Full name of responsible person**  
Judyta Zabielska  
**Position**  
assistant  
**Other areas of specialty/work**  
**Street address**  
ul. Trzy lipy 3  
**City**  
Gdańsk  
**Province**  
Pomorskie  
**Postal code**  
80-172  
**Phone**  
0048585858800  
**Fax**  
**Email**  
judyta.zabielska@invicta.pl  
**Web page address**  
invicta.pl

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Invicta Fertility and Reproductive Centre  
**Full name of responsible person**  
Judyta Zabielska  
**Position**  
assistant  
**Other areas of specialty/work**  
**Street address**

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**Fax**  
**Email**  
judyta.zabielska@invicta.pl  
**Web page address**  
invicta.pl

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Invicta Fertility and Reproductive Centre  
**Full name of responsible person**  
Judyta Zabielska  
**Position**  
assistant  
**Other areas of specialty/work**  
**Street address**  
GPNT, ul. Trzy lipy 3  
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**Email**  
judyta.zabielska@invicta.pl  
**Web page address**  
invicta.pl

## 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