# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Routine use of next generation sequencing (NGS) for preimplantation genetic diagnostics (PGD) of blastomeres obtained from embryos on day 3 in fresh IVF cycles.

## Protocol summary

**Summary**

Objective: To determine the usefulness of semiconductor-based next generation sequencing (NGS) for cleavage-stage preimplantation genetic diagnosis (PGD) of aneuploidy. Design: Prospective non randomized study. Setting: A private centers for reproductive medicine. Patient(s): 28 patients will undergo day-3 embryo biopsy with PGD and fresh cycle transfer. Additionally, 106 patients, match according to age, anti-müllerian hormone (AMH) levels, antral follicles count (AFC) and infertility duration will be selected to serve as controls. Intervention(s): Choice of the embryos for transfer will be based on the PGD NGS results. Main Outcome Measure(s): Clinical pregnancy rate (PR) per embryo transfer as primary outcome. Secondary outcome will be the implantation rate

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014070118202N2**
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**

2015-01-01, 1393/10/11

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Routine use of next generation sequencing (NGS) for preimplantation genetic diagnostics (PGD) of blastomeres obtained from embryos on day 3 in fresh IVF cycles.

**Public title**

Routine use of next generation sequencing (NGS) for preimplantation genetic diagnostics (PGD) of blastomeres obtained from embryos on day 3 in fresh IVF cycles.

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria**

Incusion: 1. Patients undergoing in vitro fertilization in Invicta Fertility and Reproductive Centre s. z o.o. in time frame from 08.2014 to 01.2015 Exclusion: 1. Patients who did not received embryo transfer in first cycle 2. Lack of data/results according to 5 verifications (that

means 6-8 week after embryo transfer)

**Age**

From **31 years** old to **38 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **28**

**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-11/14

## 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 poregnancy (as ultrasound fetal heartbeat detection)

## Secondary outcomes

### 1

**Description**

implantation rate

**Timepoint**

7 day after tansfer

**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**

Judytra 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**

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00485858 58 810

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**Web page address**

## Person responsible for scientific inquiries

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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*