

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

Inclusion: 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 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

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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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