# Among IVF-ICSI patients with poor implantation, does PGS increase pregnancy rates and live birth rates?

No registrations found.

**Ethical review**      Positive opinion
**Status**              Recruitment stopped
**Health condition type**  -
**Study type**          Interventional

## Summary

### ID

NL-OMON23652

**Source**
Nationaal Trial Register

**Brief title**
PGS, recurrent implantation failure

**Health condition**

PGS, recurrent implantation failure, IVF-ICSI

### Sponsors and support

**Primary sponsor:** UZ Brussel - Centre for Reproductive Medicine
Laarbeeklaan 101, 1090 Brussel
**Source(s) of monetary or material Support:** UZ Brussel - Centre for Reproductive Medicine
Laarbeeklaan 101, 1090 Brussel

### Intervention

### Outcome measures

**Primary outcome**

The primary outcome is the implantation rate, which is defined as the ratio between the number of gestational sacs with a fetal heartbeat and the total number of embryos transferred.

**Secondary outcome**

Secondary endpoints are embryo morphology and chromosomal status, number of transferred embryos and clinical pregnancy rate.

# Study description

### Background summary

Objective: To verify whether advantages con derive from the implementation of preimplantation genetic diagnosis for aneuploidy in patients with recurrent failed implantation, compared with conventional treatment procedures.

Design: A randomized, controlled trial.

Setting: Centre for Reproductive Medicine of the Universitair Ziekenhuis Brussel, Brussel, Belgium.

Patient(s): Two hundred patients with recurrent failed implantation were randomized into two groups. A total of 139 patients underwent ovarian stimulation, and preimplantation genetic screening was performed in 72 patients.

Intervention(s): Analysis of chromosomes X, Y, 13, 16, 18, 21 and 22 was carried out with the fluorescence in situ hybridization technique in a blastomere biopsied from day 3 embryos in the study group.

Main Outcome Measure(s): The primary endpoint is implantation rate. Secondary endpoints

are embryo morphology and chromosomal status, number of transferred embryos and clinical pregnancy rate.

Result(s): There is no significant difference of the implantation rate between the study group (18.4%) and the control group (26.8%). The number of embryos replaced is significantly lower in the control group, namely 2.1 versus 1.4 in the control group.

Conclusion(s): Preimplantation genetic screening does not increase the implantation rates after IVF-ICSI in women with recurrent failed implantation.

## Study objective

The hypothesis of the present study tries to elucidate the causes of multiple IVF failures in subfertile couples with repeated implantation failure.Therefore, these couples will undergo an IVF-cycle with or without PGS.

## Study design

Day of egg retrieval (ovum pick-up) (t=0)

Day of fertilisation (t=1)

Embryonic development and biopsy (t=3)

Day of embryo transfer (t=5)
Pregnancy outcome (t=35)

## Intervention

In both groups, patients underwent controlled ovarian hyperstimulation. IVF-ICSI was perfomed in every study patient. On day three of the embryonic development, preimplantation genetic diagnosis was performed on the embryos in the study group. The embryo transfer took place on day 5 of embryonic development.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Subfertility with need for ART with motile sperm

2. Three or more failed IVF or ICSI attempts with embryos of good morphological quality

3. Maternal age less than 38 years

4. A normal karyotype in both partners.

## Exclusion criteria

1. Maternal age above 38 years.

2. Presence of uterine pathology

# Study design

## Design

Study type:                    Interventional

| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Placebo |

## Recruitment

NL
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2001 |
| Enrollment: | 200 |
| Type: | Actual |

# Ethics review

Positive opinion
| Date: | 11-06-2008 |
| Application type: | First submission |

# Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
| --- | --- |
| NTR-new | NL1299 |
| NTR-old | NTR1347 |
| Other | UZ Brussel : 5 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A