Diagnostic efficiency and accuracy, embryonic development and clinical outcome after the biopsy of one or two blastomeres for preimplantation genetic diagnosis.

No registrations found.

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

Summary

ID

NL-OMON24785

Source
NTR

Brief title
1cell2cell

Health condition

1. Preimplantation genetic diagnosis (NLD: preimplantatie genetische diagnose);

2. blastomere biopsy (NLD: blastomeer biopsie).

Sponsors and support

Primary sponsor: Centrum Medische Genetica en Centrum Reproductieve Geneeskunde, Universitair Ziekenhuis Brussel
Vakgroep Embryologie en Genetica, Vrije Universiteit Brussel
Source(s) of monetary or material Support: Fonds voor Wetenschappelijk Onderzoek Vlaanderen
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Intervention

Outcome measures

Primary outcome

1. Embryo transfer rate;

2. Positive hCG;

3. Implantation rate;

4. Live birth rate.

Secondary outcome

1. In-vitro embryonic development after the removal of one or two blastomeres;

2. The diagnostic efficiency of both PCR- and FISH techniques for PGD.

Study description

Background summary

Preimplantation genetic diagnosis (PGD) can be considered as an alternative to prenatal diagnosis which circumvents the problem of therapeutic abortion for a genetic disease. It involves the genetic testing of blastomeres from preimplantation embryos followed by the selective transfer of embryos shown to be unaffected for the disease under study. The final goal of PGD is the birth of one healthy child and since genetic analysis is performed on one or two single blastomeres, it has to meet high standards of efficiency and accuracy. Important questions that arise are first whether the embryo development would significantly differ after the removal of only one cell as compared to two cells and secondly whether we can achieve the same level of diagnostic accuracy after the biopsy of one cell as compared to two-cell biopsy.
In order to answer these questions we enrolled patients with embryo biopsy in view of PGD or PGS in a randomized controlled trial (RCT) and assessed the diagnostic efficiency and accuracy as well as further embryonic development and clinical outcome after the removal of one or two blastomeres.

Study objective

Removal of one cell from a preimplantation embryo in view of preimplantation genetic diagnosis is less detrimental than two cell removal and will lead to a higher number of

ongoing pregnancies and births.

Study design

N/A

Intervention

Embryos were obtained from patients undergoing PGD. One or two cells were removed from embryos with more than 6 cells at day 3. Embryos shown to be free of disease were replaced in the uterus. Some surplus embryos were re-analysed to measure accuracy.

Contacts

Public
Centre for Medical Genetics, UZ Brussel, Laarbeeklaan 101
Karen Sermon
Brussels 1090
Belgium
+32 2 477 60 73
Scientific
Centre for Medical Genetics, UZ Brussel, Laarbeeklaan 101
Karen Sermon
Brussels 1090
Belgium
+32 2 477 60 73

Eligibility criteria

Inclusion criteria

PGD cycles for monogenic diseases, sexing or screening in which one or two cells can be removed from the embryos.

Exclusion criteria

PGD where two cells must be removed for accurate diagnosis: monogenic cycles where PCR for one locus is carried out, or PGD for translocation carriers.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2001
Enrollment:	592
Type:	Actual

Ethics review

Positive opinion

Date:	27-02-2007
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	NL898
NTR-old	NTR922
Other	:
ISRCTN	ISRCTN20762192

Study results

Summary results
Hum Reprod. 2008 Mar;23(3):481-92. Epub 2007 Dec 22.