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

Gepubliceerd: 27-02-2007 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24785

Bron
NTR

Verkorte titel
1cell2cell

Aandoening

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

2. blastomere biopsy (NLD: blastomeer biopsie).

Ondersteuning

Primaire sponsor: Centrum Medische Genetica en Centrum Reproductieve Geneeskunde, Universitair Ziekenhuis Brussel
Vakgroep Embryologie en Genetica, Vrije Universiteit Brussel
Overige ondersteuning: Fonds voor Wetenschappelijk Onderzoek Vlaanderen

Alphonse en Jean Forton Fonds
Onderzoeksraad Vrije Universiteit Brussel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Embryo transfer rate;
2. Positive hCG;
3. Implantation rate;
4. Live birth rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	05-01-2001
Aantal proefpersonen:	592
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-02-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL898
NTR-old	NTR922
Ander register	:
ISRCTN	ISRCTN20762192

Resultaten

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