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

**Submission date**
11/04/2007

**Recruitment status**
No longer recruiting

**Registration date**
11/04/2007

**Overall study status**
Completed

**Last Edited**
13/10/2014

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Ms Karen Sermon

**Contact details**
Centre for Medical Genetics
UZ Brussel
Laarbeeklaan 101
Brussels
Belgium
1090
+32 (0)2 477 60 73
karen.sermon@uzbrussel.be

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N/A

# Study information

### Scientific Title

### Acronym
1cell2cell

### Study objectives
Removal of one cell from a preimplantation embryo in view of preimplantation genetic diagnosis (PGD) is less detrimental than two cell removal and will lead to a higher number of ongoing pregnancies and births.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approval received from the Commission for Medical Ethics of the Academic Hospital and Faculty of Medicine and Pharmacy of the Dutch-speaking Brussels Free University (Commissie Medische Ethiek of the [then] Academisch Ziekenhuis en Faculteit Geneeskunde en Pharmacie van de Vrije Universiteit Brussel). Since then our hospital has been renamed Universitair Ziekenhuis Brussel (UZ Brussel). The study was approved on 22nd February 2001 (ref: F.W.O. 2001/05D)

### Study design
Randomised active-controlled parallel-group trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### Participant information sheet

### Health condition(s) or problem(s) studied
Preimplantation genetic diagnosis, blastomere biopsy

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

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
1. Embryo transfer rate
2. Positive human chorionic gonadotropin (hCG)
3. Implantation rate
4. Live birth rate

Outcomes were measured at 9 and 18 months.

### Secondary outcome measures
1. In-vitro embryonic development after the removal of one or two blastomeres
2. The diagnostic efficiency of both PCR and fluorescence in situ hybridisation (FISH) techniques for PGD

Outcomes were measured at 9 and 18 months.

### Overall study start date
05/01/2001

### Completion date
09/01/2005

## Eligibility

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

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
592

### Key exclusion criteria
PGD where two cells must be removed for accurate diagnosis: monogenic cycles where polymerase chain reaction (PCR) for one locus is carried out, or PGD for translocation carriers.

**Date of first enrolment**
05/01/2001

**Date of final enrolment**
09/01/2005

# Locations

**Countries of recruitment**
Belgium

Netherlands

**Study participating centre**
**Centre for Medical Genetics**
Brussels
Belgium
1090

# Sponsor information

**Organisation**
University Hospital Brussels (Universitair Ziekenhuis Brussel) (Belgium)

**Sponsor details**
Centrum Medische Genetica en Centrum Reproductieve Geneeskunde
Laarbeeklaan 101
Brussels
Belgium
B-1090

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.brusselsivf.be/default_en.aspx?lang=EN

**ROR**
https://ror.org/038f7y939

# Funder(s)

**Funder type**

Research council

### Funder Name
Research Council of the Vrije University Brussels (Onderzoeksraad Vrije Universiteit Brussel) (Belgium)

### Funder Name
Research Foundation of Flanders (Fonds voor Wetenschappelijk Onderzoek Vlaanderen [FWO]) (The Netherlands)

### Funder Name
Alphonse and Jean Forton Fund (Belgium)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Results | 01/03/2008 | | Yes | No |