

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

<b>Submission date</b> 11/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/10/2014	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Diagnostic

### **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(s)**

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.

**Key secondary outcome(s))**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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)

### 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

### 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?
<a href="#">Results article</a>	Results	01/03/2008		Yes	No