

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	<input type="checkbox"/> Prospectively registered
Registration date 11/04/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/10/2014	Condition category 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

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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