

# Multiplex ligation-dependent probe amplification And Karyotyping: an Evaluation

<b>Submission date</b> 22/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/06/2008	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

**Study website**  
<http://www.makestudy.nl>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

80-007029-98-07-047

# Study information

## Scientific Title

## Acronym

MAKE

## Study objectives

The present study will evaluate the hypothesised equivalent pre-clinical diagnostic accuracy of Multiplex Ligation-dependent Probe Amplification (MLPA) compared to karyotyping in a clinical setting.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the local ethics committee (Medisch Ethische Toetsings Commissie) on the 21st August 2006 (ref: WO 06.032).

## Study design

Prospective study of two paired diagnostic tests.

## Primary study design

Interventional

## Secondary study design

Multi-centre

## Study setting(s)

Not specified

## Study type(s)

Diagnostic

## Participant information sheet

## Health condition(s) or problem(s) studied

Trisomy 13, Trisomy 21, Fetal aneuploidies, Trisomy 18, Sex chromosome abnormalities

## Interventions

In each patient, amniotic fluid is assessed with MLPA (experimental diagnostic test) and Karyotyping (gold standard).

## MPLA:

MLPA is a molecular genetic technique in prenatal diagnosis using amniotic fluid. In this study a commercially available kit, P095 is used (produced by MRC Holland and widely tested).

The MLPA-result is known in two to four days. To perform MLPA 2 - 4 ml of amniotic fluid is required. Such an amount is available since routinely 15 - 20 ml of amniotic fluid is obtained.

If there is too little amniotic fluid (less than 12 ml), MLPA will not be carried out in the study.

Karyotyping:

Karyotyping is carried out without any changes. The result is known in two to three weeks.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

1. Diagnostic accuracy
2. Technical performance (inconclusive or missing results)
3. Technical capacity

### **Secondary outcome measures**

1. Patient anxiety and distress
2. Cost-effectiveness
3. Unexpected findings
4. Patient preference

### **Overall study start date**

01/02/2007

### **Completion date**

01/01/2009

## **Eligibility**

### **Key inclusion criteria**

1. Amniocentesis is performed
2. The referral indication is advanced maternal age and/or increased risk after PreNatal Screening (PNS)
3. Aged more than or equal to 18 years
4. No language barriers
5. Informed consent is given
6. Singleton pregnancies

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

4500 paired MLPA-Karyotyping test results

**Key exclusion criteria**

Other referral indications:

1. Parent(s) with chromosome aberration
2. Ultrasound abnormalities
3. Previous child with chromosome aberration

**Date of first enrolment**

01/02/2007

**Date of final enrolment**

01/01/2009

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Onze Lieve Vrouwe Gasthuis (OLVG)

Amsterdam

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**Sponsor information****Organisation**

Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

**Sponsor details**

Department of Obstetrics and Gynaecology

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.olvg.nl/>

**ROR**

<https://ror.org/01d02sf11>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

### Alternative Name(s)

Netherlands Organisation for Health Research and Development

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

Netherlands

## 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?
<a href="#">Protocol article</a>	Protocol	20/05/2008		Yes	No