

Multiplex ligation-dependent probe amplification And Karyotyping: an Evaluation

Submission date 22/01/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/06/2008	Condition category 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

Contact information

Type(s)
Scientific

Contact name
Ms Elisabeth Boormans

Contact details
Onze Lieve Vrouwe Gasthuis (OLVG)
Department of Obstetrics and Gynaecology
P.O. Box 95500
Amsterdam
Netherlands
1090 HM
+31 (0)20 599 3477
e.m.a.boormans@olvg.nl

Additional identifiers

Protocol serial number
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).

Primary study design

Interventional

Study design

Prospective study of two paired diagnostic tests.

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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

Netherlands

1090 HM

Sponsor information

Organisation

Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

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

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?
Protocol article	Protocol	20/05/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes