ISRCTN47252164 https://doi.org/10.1186/ISRCTN47252164

Multiplex ligation-dependent probe amplification And Karyotyping: an Evaluation

Submission date 22/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/01/2007	**Overall study status** Completed	
Last Edited 03/06/2008	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.makestudy.nl

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

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
Netherlands
1090 HM

Sponsor information

Organisation
Onze Lieve Vrouwe Gasthuis (OLVG) (The Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology
P.O. Box 95500
Amsterdam
Netherlands
1090 HM

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?
Protocol article	Protocol	20/05/2008		Yes	No