Trophoblast Retrieval and Isolation from the Cervix to study genetic birth defects

Published: 06-03-2018
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON50229

Source
ToetsingOnline

Brief title
TRIC-PT

Condition

- Chromosomal abnormalities, gene alterations and gene variants

Synonym
Genetic Birth Defect; Congenital Genetic Anomaly

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cervix, genetic birth defect, Pap smear, Trophoblast

Outcome measures

Primary outcome

Genetic test outcome in DNA samples obtained by TRIC is the same as in samples

obtained by CVS.

Secondary outcome

NA

Study description

Background summary

The Non-Invasive Prenatal Testing (NIPT) allows early diagnosis of trisomies with high sensitivity and specificity. However, it does have some limitations; the fetal fraction must reach over 4% for accurate testing, an issue in e.g. maternal obesity. Secondly, the low fetal fraction makes this technique highly challenging in detecting a birth defect of genetic origin other than trisomies. Prenatal testing for the other genetic birth defects is currently performed on samples obtained invasively by chorionic villous sampling (CVS) or amniocentesis, which have a 0.3-0.5% miscarriage risk. A new non-invasive technique named TRIC is based on the principle that fetal trophoblast-like cells are naturally shed from the placenta into the reproductive tract. By endocervical sampling with a Papanicolaou (Pap) smear, intact fetal cells can be collected as early as 5 weeks of gestation in number sufficient for genetic testing. However, this technique has not yet been compared to the current gold standard of sampling, CVS.

Study objective

Main objective is to investigate if fetal DNA samples non-invasively obtained by the TRIC method provide the same prenatal genetic test result as diagnostic testing performed on samples obtained invasively by CVS, currently the gold standard. This will be done by performing the TRIC method at the time of CVS sampling to test if the genetic test result in samples obtained by TRIC are the same as from samples obtained by CVS.

Study design

Non-inferiority study.

Study burden and risks

The burden consists of undergoing endocervical sampling (Papanicolaou smear) at intake counselling and/or directly before CVS sampling. The additional risk is harmless self-limited vaginal spotting. No significant increased risk of serious adverse outcomes nor any trend in that direction have been observed in previous studies.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) 18 years or above
2) Have a referral for CVS sampling
3) Pregnant with a gestational age between 5 and 20 weeks

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2018
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	06-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63811.018.17