Clinical validation of fetal RHD genotyping in gestational week 27.

Published: 13-08-2021
Last updated: 14-03-2025

1. Validation of the currently used fetal RHD genotyping platform according to IVDR 2017/746 guidelines;2. Validation of an adapted fetal RHD genotyping platform (different liquid handling system and DNA isolation kit) according to IVDR 2017/746...

Ethical review	Approved WMO
Status	Completed
Health condition type	Foetal complications
Study type	Observational invasive

Summary

ID

NL-OMON54455

Source
ToetsingOnline

Brief title
Clinical validation of fetal RHD genotyping in gestational week 27.

Condition

- Foetal complications

Synonym
Hemolytic Disease of the Fetus and Newborn/Rhesus Disease

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Diagnostiek B.V.
Source(s) of monetary or material Support: het Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Intervention

Keyword: Noninvasive Prenatal Testing, Real-Time Polymerase Chain Reaction, Rh Isoimmunization, Rho(D) Immune Globulin

Outcome measures

Primary outcome

Accuracy of fetal RHD genotyping in comparison to the reference standard as measured by the sensitivity, specificity, false negative rate, false positive rate, positive predictive value, negative predictive value, proportion of technical failures.

Secondary outcome

Not applicable.

Study description

Background summary

By May 2022, all in vitro diagnostic medical devices will need to comply with the new EU Regulation 2017/746 on in vitro diagnostic medical devices (IVDR). This regulation also applies to the non-invasive fetal RHD genotyping platform at Sanquin Diagnostic Services in Amsterdam, which is since 2011 used for the national antenatal population screening program PSIE (Prenatal Screening for Infectious Diseases and Erythrocyte Immunisation). In order to become IVDR 2017/746 compliant and obtain CE marking, the current routinely used RHD genotyping platform at Sanquin needs to be clinically revalidated in accordance with IVDR 2017/746.

Study objective

1. Validation of the currently used fetal RHD genotyping platform according to IVDR 2017/746 guidelines;
2. Validation of an adapted fetal RHD genotyping platform (different liquid handling system and DNA isolation kit) according to IVDR 2017/746 guidelines.

Study design

Prospective assessment of the platform*s fetal RHD genotyping accuracy in comparison to the reference standard.

Study burden and risks

The collection of one tube of cord blood immediately after delivery has minimal impact on mother and child, since venipuncture of the umbilical cord will be performed after clamping of the cord. Also, the collection of an extra tube of blood during the regular blood collection appointment in GW27 represents no significant burden to the pregnant mother, since both the regular and extra blood tube will be collected in one and the same venipuncture procedure and taking into account the small volume of 10 mL of blood. Finally, data collection concerns fetal RHD genotyping, which is already part of the national antenatal population screening program and only women participating in this program will be approached for the study. The study can only be performed with the group of pregnant RhD-negative women and will provide a benefit to this group in terms of quality assurance of the RHD genotyping platform at Sanquin.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Pregnant
RhD-negative
Women should be eligible for the 27th gestational week (GW27) pregnancy screening.

Exclusion criteria

Not applicable.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-01-2022
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	13-08-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	28-10-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	16-03-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	09-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL77102.058.21