Genetic immunological causes of recurrent miscarriages; 'HLA sharing as a cause of recurrent miscarriages'

Published: 04-07-2012
Last updated: 28-09-2024

Does HLA sharing in couples with recurrent miscarriage play a role in recurrent miscarriage of unknown etiology?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Abortions and stillbirth
Study type	Observational invasive

Summary

ID

NL-OMON39578

Source
ToetsingOnline

Brief title
REMI-I-1

Condition

- Abortions and stillbirth

Synonym
Abortions, Recurrent miscarriages

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Genetic factors, HLA sharing, Immunology, Recurrent miscarriages

Outcome measures

Primary outcome

Distribution and prevalence of: HLA sharing, KIR genotype, polymorphism of progesteronreceptor, mutations of complement regulatory genes and HLA antibodies

Secondary outcome

Pregnancy-outcome and complications

Study description

Background summary

Recurrent miscarriages is commonly defined as three or more consecutive miscarriages prior to the 20th week. It is a common problem affecting 1 to 2% of all fertile couples and is a highly heterogeneous condition. An underlying cause may be identified in about 25-50% of cases. Therefore 50-75% of the couples are left with the burden of continuous uncertainty and clinicians without means to treat these women. In the last decade several therapies were investigated, however none of these therapies have been proven effective.
In this project we aim to determine different genetic immunological causes of recurrent miscarriage of unknown etiology. These results will help to identify these patients and to eventually develop effective therapies.

Study objective

Does HLA sharing in couples with recurrent miscarriage play a role in recurrent miscarriage of unknown etiology?

Study design

A case control study in genetic immunological risk factors

Study burden and risks

Women will be asked to fill out an extended, personal questionnaire (25 minutes)
Bloodsamples will be taken from women and their partners 1 time
If a couples already has child(ren) permission will be asked to take a buccal schwab
We do not expect that participating in this trial will be a burden or be of any risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Recurrent miscarriages (>2 and < 20 weeks)
Age < 36 years

Exclusion criteria

Parental chromosomal abnormalities
Uterus anomalies

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2012
Enrollment:	432
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	11-02-2014
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	NL40519.058.12
Other	volgt nog