

Immunological causes of recurrent miscarriages.

Published: 18-06-2012

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Does humoral and/or cellular rejection play a role in recurrent miscarriage of unknown etiology? Can biomarkers of humoral and/or cellular rejection be used for the detection of patients who are likely to suffer a miscarriage in a next pregnancy?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON44802

Source

ToetsingOnline

Brief title

REMI-I-2

Condition

- Autoimmune disorders
- 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, Donatie NVLE.

Intervention

Keyword: Biobanking, Immunology, Recurrent miscarriages

Outcome measures

Primary outcome

Pathophysiology, with focus on immunology of recurrent miscarriages.

Secondary outcome

Pregnancy outcome

Study description

Background summary

Recurrent miscarriage 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 are investigated however none of these therapies has been proven effective. In the first part of this project we aim to determine different 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 humoral and/or cellular rejection play a role in recurrent miscarriage of unknown etiology?

Can biomarkers of humoral and/or cellular rejection be used for the detection of patients who are likely to suffer a miscarriage in a next pregnancy?

Study design

- 1) A biobank of new couples attending the recurrent miscarriage clinic
- 2) A prospective cohort study to perform functional test with maternal peripheral blood mononuclear cells

Study burden and risks

No experimental medication will be used.

Women will be treated according to local hospital protocol. No additional physical examination is needed for this study.

Blood samples will be taken from the subjects and their partners. In addition women will be asked to collect menstrual fluid during their period.

Partners will also be asked to collect semen one time. No additional risks or burden are expected from the study.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Recurrent miscarriages (>2 subsequently)

Age < 40

Age >18

Exclusion criteria

Uterus anomalies
Parental chromosomal abnormalities
Cervix insufficiency
Patient mentally or lagally incapacity
Untreated thyroid disease
Poor balance or treatment of DM
History of recent alcohol or drugsabuse
ART (assisted reproductive technology) pregnancies

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:	Recruiting
Start date (anticipated):	01-07-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO	
Date:	18-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 07-10-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 15-12-2017

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	NL38275.058.11