Peripartum Cardiomyopathy Registry Biomarker sub-protocol

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Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON43678

Source
ToetsingOnline

Brief title
PPCM Registry

Condition

- Myocardial disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Peripartum cardiomyopathy, pregnancy related heart failure

Research involving
Human

Sponsors and support

Primary sponsor: European Society of Cardiology
Source(s) of monetary or material Support: European Society of Cardiology - EURObservational Research Programme

Intervention

Keyword: Biomarkers, Peripartum cardiomyopathy

Outcome measures

Primary outcome

The primary objective of this registry is to describe the epidemiology and prognosis of outpatients and inpatients with PPCM and the diagnostic and therapeutic processes.

Secondary outcome

The registry will serve to identify parameters that serve as diagnostic and prognostic markers* these may be useful for identification and risk stratification. Biomarkers such as NT-proBNP, Soluble ST2, Galectin -3, metalloproteinases, C-reactive protein and other biomarkers that may arise to be potentially important during the execution of this study, will be evaluated.

Study description

Background summary

Peripartum cardiomyopathy is a rare but potentially life-threatening form of heart failure affecting women late in pregnancy or in the first months after delivery. Peripartum cardiomyopathy is difficult to diagnose and its onset and progression are variable between individuals. The pathophysiology remains poorly understood, hence treatment options are limited and possibly harmful to the foetus. Furthermore, geographical incidence varies greatly and little is known about the incidence in Western countries. To gain further understanding of the pathophysiology and incidence of peripartum cardiomyopathy, the European Society of Cardiology initiated a study group to implement a registry.

The aim of the Peripartum Cardiomyopathy Registry was to describe the demographic, clinical, and biological characteristics of outpatients and inpatients with PPCM followed by a representative setting of cardiology centres. The protocol of the Peripartum Cardiomyopathy (PPCM) Registry has

recently been amended to incorporate a sub-protocol that aims, through some blood analyses, at better understanding this disease in pregnant women or post-partum.

Study objective

The purpose of the sub-study is to do research into markers which will hopefully assist to diagnose the condition Peripartum Cardiomyopathy as early as possible. The blood donated for research will also assist in the assessment of women having a high risk of not recovering their
heart muscle function. This blood will be used to establish if markers of inflammation and fibrosis contribute to the cause and progression of disease.

Study design

The PPCM Registry is a prospective, multicentre, observational study of patients presenting to Cardiology Centres in European, Mediterranean countries and other international centres.

The registry, on about 1000 cases of suspected PPCM, aims to collect data on the clinical phenotype, social status, frequency, diagnosis and differential diagnosis, forms of care and treatment of heart failure across a wide variety of countries by internal medicine specialists or cardiologists and other specialists who manage patients with PPCM. The Case Report Form (CRF) will be accessed through the EORP website.

Standard management of patients will be the diagnostic and therapeutic interventions currently performed in each centre for patients presenting with signs and symptoms of PPCM. Drug prescriptions and indications to perform diagnostic/ therapeutic procedures will be completely left to participating cardiologists* decision. No specific protocols or recommendations for evaluation, management, and/or treatment will be put forth during this observational study.

Current sub-study:
Centres can participate in this sub-study if they have at least 10 patients and if they have access to a freezer at -80°C for conservation of the samples. The centres will have to store the samples for one year until the requested number is reached. Then the samples will be shipped
all together. Blood will be collected at baseline and at 6 months.

Study burden and risks

For this study, blood samples (2 tubes, 13 mL blood) will be obtained at two different time points. All other
investigations in this study are part of routine clinical care. Therefore,

risks for the patients can be considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with peripartum cardiomyopathy
1. peripartum stage
2. Signs and/or symptoms of heart failure
3. Ejection fraction <45%

Exclusion criteria

Other cause of heart failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-04-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL55033.078.15