# MEnopause and Raloxifen in ischaemic Coronary disease: effects on Endothelial Dysfunction

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
31/01/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
26/04/2007	Completed	[X] Results
<b>Last Edited</b> 09/05/2019	Condition category Circulatory System	Individual participant data

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Magda Heras

#### Contact details

Department of Cardiology Hospital Clínic of Barcelona Barcelona Spain 08036

# Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$ 

**Secondary identifying numbers** 03-0579

# Study information

#### Scientific Title

MEnopause and Raloxifen in ischaemic Coronary disease: effects on Endothelial Dysfunction

#### **Acronym**

**MERCED** 

#### **Study objectives**

Treatment with raloxifen improves vascular reactivity in menopausal patients with ischaemic coronary disease. This improvement can be measured reliably by non-invasive methods.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approval received from the ethics committee of the Spanish Drug Agency (Agencia Espanola del Medicamento) on the 2nd March 2004 (ref: 03-0579).

#### Study design

This study is a national, multicentre, double blind, cross-over study, with randomly assigned periods

# Primary study design

Interventional

## Secondary study design

Single-centre

# Study setting(s)

Not specified

# Study type(s)

**Treatment** 

#### Participant information sheet

# Health condition(s) or problem(s) studied

Ischaemic heart disease in postmenopausal women

#### **Interventions**

Patients will be given 60 mg per day of raloxifen or placebo for three months, there is a one-month washing period and they are crossed to the other treatment (raloxifen for those who received placebo and palcebo for those treated with raloxifen) for another three months. Patients and researchers will be blinded to the treatment throughout the trial. At the end of each period, the endothelial dependent vasodilatation will be measured together with several markers of disease (includig inflammation and thrombosis).

#### **Intervention Type**

Drug

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

Raloxifen

#### Primary outcome measure

To determine the effect of the three-months treatment with raloxifen versus placebo on endothelial function (humeral artery) in postmenopausal women with confirmed ischaemic heart disease.

## Secondary outcome measures

To determine the effect of raloxifen on:

- 1. Coagulation fibrinolysis system
- 2. Platelet aggregation
- 3. Adhesion mollecules
- 4. Cytokines
- 5. C-Reactive Protein (CRP)
- 6. Lipid profile

## Overall study start date

01/01/2004

#### Completion date

31/07/2005

# **Eligibility**

#### Key inclusion criteria

- 1. Postmenopausal women, aged less than 70 years
- 2. Estradiol and Follicle Stimulating Hormone (FSH) plasma concentrations less than 30 pg/mL and more than 40 UI/L, respectively
- 3. Confirmed coronary artery disease by coronary angiography (at least one vessel with stenosis more than 70%) and/or previous myocardial infarction
- 4. Signature of the informed consent to participate in the study and to undergo all the tests included in the trial

# Participant type(s)

Patient

#### Age group

Adult

#### Sex

Female

# Target number of participants

60

#### Total final enrolment

#### Key exclusion criteria

- 1. History of gynaecological or other conditions that contraindicate treatment with raloxifen:
- a. Deep vein thrombosis, pulmonary embolism, retina venous thrombosis
- b. Hypersensitivity to raloxifen
- c. Increase of hepatic enzymes including colestasis
- d. Undiagnosed endometrial bleeding
- e. Endometrial cancer
- f. Breast cancer
- 2. Kidney failure (creatinine greater than 2 mg/dl)
- 3. Participation in another clinical study during 30 days prior to the randomisation
- 4. Hormone replacement therapy in the last six months

#### Date of first enrolment

01/01/2004

#### Date of final enrolment

31/07/2005

# Locations

#### Countries of recruitment

Spain

# Study participating centre Department of Cardiology

Barcelona Spain 08036

# Sponsor information

#### Organisation

Hospital Clínic of Barcelona (Spain)

# Sponsor details

c/o Dr Magda Heras Villarroel 170 Barcelona Spain 08036

# Sponsor type

Hospital/treatment centre

#### ROR

https://ror.org/02a2kzf50

# Funder(s)

# Funder type

Government

#### Funder Name

This work was funded in part by the Ministerio de Sanidad y Consumo, Instituto de Salud Carlos III (Spain) (ref: Red HERACLES REDG03/045-0 and PI050038)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011	09/05/2019	Yes	No