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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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).

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
33

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)

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

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