

Hormone replacement therapy and cardiovascular disease: influence of oestrogen replacement therapy on chest pain

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/10/2019	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J McLenachan

Contact details
Leeds General Infirmary
Department of Cardiology
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 2926476
Jim.McLenachan@leedsth.nhs.uk

Additional identifiers

Protocol serial number
VCO500 J458 448505

Study information

Scientific Title

Hormone replacement therapy and cardiovascular disease: influence of oestrogen replacement therapy on chest pain

Study objectives

Angina in post-menopausal women is a common clinical problem that is often under-investigated and under-treated. While most women with angina have atherosclerotic coronary disease, many have angina with anatomically normal coronary arteries (so-called Syndrome X). Those women with angina and coronary artery disease have a high risk of major cardiovascular events including unstable angina, myocardial infarction and death. Indeed, recent evidence suggests that while coronary disease is declining in men, the incidence of major events continues to rise in women, and may equal that of men in less than two decades. Women with angiographically normal coronary arteries present a different problem; although they have a good prognosis, their symptoms do not respond well to conventional anti-angina therapy and their morbidity and hospital re-admission rate is high. Hormone replacement therapy (HRT) with oestrogen reduces the incidence of cardiac events in post-menopausal women by up to 50%, by mechanisms that have not been elucidated. Interest has recently focused on the functions of the innermost layer of the coronary artery, the coronary endothelium. In health, the endothelial cells cause the artery to dilate in response to a number of physical and chemical stimuli. This function, called endothelium-dependant vasodilation, is lost in the early phase of coronary atherosclerosis and may precipitate further vascular damage. In animal models, HRT given to oophorectomised females can restore normal endothelial function, and may retard the development of atherosclerosis. An analogous abnormality in the endothelial control of coronary blood flow has been identified in Syndrome X. In neither case has the effect of HRT on coronary artery responsiveness been studied in humans. Nor has there been investigation of the effect of HRT on symptoms (i.e. chest pain, exercise tolerance) in either women with or without coronary disease. We plan to assess the influence of HRT on coronary artery responses in post-menopausal women with angina, both with and without coronary artery disease, in an unblinded single angiographic study. Ischaemic heart disease accounts for 24% of all deaths in women aged between 55-74, being the largest single cause of death in this group. The potential benefit to the nation, in both health and financial terms, of more effective therapy and prevention of this burden of disease is great. This study aims to examine mechanisms by which HRT might prevent death and other major cardiovascular events, as well as exploring for the first time the therapeutic potential of HRT in the treatment of chest pain in with and without coronary artery disease. The information acquired may provide the basis for larger controlled trials of HRT as symptomatic and preventative therapy for heart disease in post-menopausal women.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Cardiovascular diseases: heart disease

Interventions

Not provided at time of registration

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/09/1996

Eligibility**Key inclusion criteria**

Post-menopausal women with angina

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

08/01/1994

Date of final enrolment

30/09/1996

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Leeds General Infirmary

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration