

The Women's Hormone Intervention Secondary Prevention Pilot Study

Submission date 25/10/2000	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/10/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/09/2008	Condition category Circulatory System	☐ Individual participant data

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
G9811667

Study information

Scientific Title

Acronym
WHISP

Study objectives

To determine the safety and tolerability of hormone replacement therapy (HRT) after acute myocardial infarction (MI) in post-menopausal women

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 18/07/2007: North Thames Multicentre Research Ethics Committee and the Local Research Ethics Committee at each centre.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Acute myocardial infarction (MI)

Interventions

Not provided at time of registration

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Reinfarction, readmission, death

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2000

Eligibility**Key inclusion criteria**

Post menopausal women (amenorrhoea for more than 12 months oestrogen deficiency symptoms) or more than 55 years, more than 48 hours and less than 7 days after the onset of acute Myocardial Infarction (MI) (Creatine Kinase [CK] twice upper limit or CKMB above the threshold considered diagnostic for myocardial damage in that centre) plus one of the two additional following criteria:

1. Admission for symptoms of acute myocardial ischaemia

2. Changes on the electrocardiogram supportive of a diagnosis of acute MI, provision of written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Unconfirmed MI
2. Use of HRT currently or previous 12 months, patients for whom clear indications for, of contraindications to, long term HRT
3. Increased risk of thromboembolism
4. Prior history of DVT or PE
5. BMI more than 32
6. Prolonged immobility
7. Known breast or endometrial cancer
8. Post-menopausal bleeding that has not been adequately investigated
9. Presence of non-cardiac condition influencing survival
10. Anticipated inability of the patient to comply with the study procedures

Date of first enrolment

01/10/1999

Date of final enrolment

01/12/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Clinical Trials & Evaluation Unit

London

United Kingdom

SW3 6NP

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	01/09/2006		Yes	No