

Cardiovascular risk factors in post menopausal woman: The effect of mode of delivery of hormone replacement therapy (HRT)

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 21/12/2009	Condition category Circulatory System	<input type="checkbox"/> 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

Study information

Scientific Title

Study objectives

To establish differences, if any, in alteration in cardiovascular risk factors with HRT in post menopausal women according to route of administration of HRT, oral, transdermal and implant, using first oestrogen alone then oestrogen plus norethisterone, or testosterone for implant. There is increasing use of HRT by post menopausal women. Observational epidemiological studies in the United States but no randomised controlled trials of HRT have been carried out in the primary practice setting. Previous studies of cardiovascular risk factors have shown a variety of responses according to type of progestagen and oral or topical administration. None has examined the effect of route using identical progestagen.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised open label controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypertension, menstrual disorders and hormone replacement therapy (HRT)

Interventions

Menopausal status was confirmed and women were randomised to one of three treatment groups or acted as controls. The treatment regimes were two oral groups, with cyclical or continuous progestagen, and one transdermal regime with cyclical progestagen. The group who had had a hysterectomy received HRT by implant. Each regime lasted six months: for the first 3 months, oestradiol unopposed was given by each route; for the second three months, norethisterone was added as the progestagen, orally and transdermally as appropriate.

Measurements: Blood samples

1. fasting glucose
2. insulin
3. total cholesterol
4. high-density lipoprotein (HDL) cholesterol
5. low-density lipoprotein (LDL) cholesterol and triglycerides
6. lipoprotein (a)
7. follicular stimulating hormone
8. lutenising hormone
9. oestradiol
10. factor VII
11. fibrinogen
12. plasmin antiplasmin
13. thrombin anti thrombin
14. Von willebrand factors
15. E-selectin

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oestradiol, norethisterone, testosterone

Primary outcome(s)

1. Response to HRT
2. Anthropometric measurements
3. Cardiovascular Risk Factors
4. Blood pressure
5. Lipoproteins
6. Glucose and insulin
7. Clotting variables
8. Arterial wall factors

Key secondary outcome(s)

Not provided at time of registration

Completion date

13/03/2000

Eligibility**Key inclusion criteria**

Women aged 50 - 65 years from lists in general practices local to the Charing Cross Hospital Lipid Clinic in West London.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

Female

Key exclusion criteria

Women with liver, renal or endocrine abnormalities were excluded, as were those on lipid altering medication.

Date of first enrolment

01/02/1995

Date of final enrolment

13/03/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Cardiovascular Medicine**

London

United Kingdom

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Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Cardiovascular Disease and Stroke National Research and Development Programme (UK)

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?
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[Results article](#)

results

01/12/2000

Yes

No