

# An effect of hormone replacement therapy on cataract and glaucoma in postmenopausal women.

<b>Submission date</b> 04/06/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/05/2021	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cataracts are cloudy patches that develop in the lens of your eye. The lens is a structure that is found just behind your pupil (the black circle of your eye) and it lets in light to the back of your eye (the retina). If the lens becomes cloudy with a cataract, this light cannot get through so efficiently, and this can cause blurred or misty vision. If left untreated, blindness can eventually result. Cataracts are, in fact, the leading cause of impaired vision and blindness worldwide. Postmenopausal women are at a higher risk of developing cataracts when compared to men of the same age group. Scientists think this may be because the female sex hormone oestrogen has a protective effect on the eye, helping to prevent cataracts. However, some studies have shown that postmenopausal women currently taking hormone replacement therapy (HRT), or have taken HRT in the past, are at an even higher risk of developing cataracts. Glaucoma is another common eye condition that can lead to impaired vision and blindness. It is caused by a blockage of the eyes drainage tubes (trabecular meshwork). This stops the eye fluid (aqueous humour) from draining properly, leading to an increase in pressure within the eye (intraocular pressure). This can cause damage to the optic nerve and light-sensitive nerve tissue found at the retina. Low oestrogen levels in postmenopausal women puts them at a higher risk of developing glaucoma, but some studies have suggested that HRT helps to prevent this. This study aims look at the effect of HRT on the development of cataracts and glaucoma.

### What does the study involve?

Participants are placed into one of two groups. Group 1 includes postmenopausal women who have never used HRT and group 2 includes postmenopausal women who have used HRT continuously for more than 5 years. They will undergo tests over a 6 month period which will measure lens opacity (how cloudy the lens is) and optic nerve cupping (a way to measure possible damage to the optic nerve and loss of nerve fibres), look at the nerve fibres lining the retina (retinal nerve layer Optical Coherence Tomography or OCT), measure serum inflammatory cytokines (a way of measuring inflammation) and antioxidant levels.

### Who can take part?

Women who went through the menopause at least 5 years ago.

When does the study take place?

June 2012 to March 2014

Where does the study take place?

The study has been set up by the Bucheon St. Mary's Hospital (South Korea)

What are the possible benefits and risks to participants?

There are no possible benefits or risk to participants.

Who is funding the project?

National Research Foundation of Korea (NRF) - (South Korea)

Who is the main contact?

Professor Eun Chul Kim

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## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Eun Chul Kim

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

**Scientific Title**

An effect of hormone replacement therapy on cataract and glaucoma in postmenopausal women: A parallel group, case-control study

**Study objectives**

Women have been reported to have a lower vision than men of same age. Several studies have reported that postmenopausal women have a higher prevalence of cataract and glaucoma than men of similar age. The definite relationship between gender and cataract prevalence was unclear, but it suggests female sex hormone may play an important role in protecting cataract and glaucoma progression.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Institutional Review Board (IRB) / Ethics Committee of Bucheon St. Mary Hospital, 3/2/2012, ref. HC13RISI0026

**Study design**

Parallel group, case-control study

**Primary study design**

Interventional

**Secondary study design**

Case-control study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Cataract and glaucoma

**Interventions**

Hormone replacement therapy

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Cortical, nuclear, and posterior subcapsular density, pentacam nucleus staging (PNS), pentacam densitometry of zone (PDZ) measured by pentacam.

**Secondary outcome measures**

Antioxidant and inflammatory cytokines activities in serum.

**Overall study start date**

01/06/2012

**Completion date**

01/03/2014

## Eligibility

**Key inclusion criteria**

Eligible patients included postmenopausal women at least 5 years of postmenopausal period, who either:

1. Never used HRT (Group 1: 128 patients) after menopause
2. Continuously used HRT (Group 2: 136 patients) for more 5 years from menopause

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Group 1: 128 patients, Group 2: 136 patients

**Total final enrolment**

264

**Key exclusion criteria**

1. A history of any ocular injury or disorder
2. An infection, inflammation, surgery within the prior 6 months
3. Any uncontrolled systemic disease, or significant illness

**Date of first enrolment**

01/06/2012

**Date of final enrolment**

01/03/2014

## Locations

**Countries of recruitment**

Korea, South

**Study participating centre**

Bucheon St. Mary's Hospital

Bucheon

Korea, South  
420-717

## Sponsor information

### Organisation

Bucheon St. Mary's Hospital (South Korea)

### Sponsor details

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### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/01fpnj063>

## Funder(s)

### Funder type

Government

### Funder Name

National Research Foundation of Korea (NRF) funded by the Ministry of Science, ICT & Future Planning (No. 2012R1A1A1038648) (South Korea)

### Funder Name

Institute of Clinical Medicine Research of Bucheon St. Mary's Hospital, Research Fund, BCMC13LH03 (South Korea)

## 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?
<a href="#">Abstract results</a>		01/06/2015	10/05/2021	No	No