ISRCTN72439325 https://doi.org/10.1186/ISRCTN72439325

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

Submission date
04/06/2014

Recruitment status
No longer recruiting

Registration date
18/06/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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
eunchol@hanmail.net

Contact information

Type(s)
Scientific

Contact name
Prof Eun Chul Kim

Contact details
Bucheon St. Mary's Hospital
327 Sosa-ro
Wonmi-gu
Gyeonggi-do
Bucheon
Korea, South
420-717

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 a 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
c/o Prof. Eun Chul Kim
Department of Ophthalmology
Bucheon St. Mary's Hospital
327 Sosa-ro
Wonmi-gu
Gyeonggi-do
Bucheon,
Korea, South
420-717

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?
Abstract results		01/06/2015	10/05/2021	No	No