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Mongolia glaucoma screening trial

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Registration date 28/03/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/02/2016	**Condition category** Eye Diseases	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Glaucoma is a common eye condition that causes damage to the optic nerve (the nerve which carries messages between the eye and the brain), affecting vision. One of the main causes of glaucoma is increased pressure in the eye (intraocular pressure), which can happen suddenly or gradually over time. Vision loss caused by glaucoma is irreversible, and so it is very important to discover it early so it can be treated. One of the less common types of glaucoma is primary angle closure glaucoma (PACG). The eyeball is filled with a liquid called the aqueous humour, which maintains the correct pressure and keeps the eye in the right shape. This fluid constantly flows in an out of the eye through a complex drainage system. In PACG, this drainage system suddenly becomes blocked because the edge of the iris (coloured part of the eye) touches the cornea (transparent layer at the front of the eye), causing the pressure inside the eye to increase rapidly. This type of glaucoma comes on very suddenly and is usually very painful, and so it would be beneficial to be able to find out if someone is likely to develop it so they can be closely monitored. One way of doing this is to use advanced screening techniques, so that the space between the iris and cornea can be measured. The aim of this study is to find out whether measuring this space with an ultrasound probe (ultrasound central anterior chamber depth, cACD) is a good way of predicting whether someone is likely to develop PACG.

Who can participate?
Healthy adults aged 50 and over who live in and around the town of Bayanhongor in south west Mongolia and from three districts of Ulaanbaatar city (Mongolia).

What does the study involve?
At the start of the study, all participants have an eye exam in order to make sure they do not have glaucoma already. Participants then are randomly allocated to one of two groups. Those in the first group received further screening using the ultrasound central anterior chamber depth (cACD) technique. This involves using an ultrasound probe (scanning device which uses sound waves) to determine the space between the iris (coloured part of the eye) and the innermost surface of the cornea (transparent layer at the front of the eye). The measurement can then be used to predict to risk of the participant developing PACG. Those in the second group do not receive any further screening. After six years, all participants are followed up in order to find out how many have developed PACG.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study is run from the International Centre for Eye Health, London (UK) and takes place in three districts of Ulaan Baatar (Sukbaatar, Bayanzurkh and Chingltei) and Bayanhongor (Mongolia)

When is the study starting and how long is it expected to run for?
March 1999 to October 2015

Who is funding the study?
1. Wellcome Trust (grant reference: 075110) (UK)
2. Christian Blind Mission International (Germany)
3. British Council for Prevention of Blindness (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Randomised controlled trial of screening for primary angle closure in Mongolia

Study objectives
Screening with central anterior chamber depth and prophylactic treatment with laser peripheral iridotomy can reduce the five year incidence of Primary Angle Closure Glaucoma (PACG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval granted for both baseline and follow up studies: all forms can be forwarded.
1. For baseline study approval was received from Local Ethics Board in Mongolia and Institute of Ophthalmology, university College, London. There was an ongoing agreement between the institue of Ophthalmology and the Mongolian Ministry of Health for eye research that covered the baseline study in 1999.
2. For follow up study: approval granted from London School of Hygiene and Tropical Medicine (approval form 1084) on the 3rd April 2004, and local ethics board in Mongolia in September 2005.

Primary study design
Interventional

Study design
Single masked randomised controlled trial in Mongolia.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary Angle Closure Glaucoma

Interventions
Sample size:
Incident PACG was calculated (based on the method described by Leske et. al.). The study was designed with 85% power to detect a 70% reduction in the estimated five-year incidence of 1.4% at the 5% significance level. Allowing for approximately 33% loss to follow up, a total sample size of 5000 was required.

Randomisation:
Sequence of randomisation was computer generated in blocks of 50 for each individual into either intervention or control arm. This was written onto a piece of paper in London, inserted into an enumerated envelope and sealed by a co-worker not involved with the field work. The envelope with the corresponding number was opened after a registration number had been assigned to the participant.

Registration:
All participants records were hand written in a book with study number, name, gender, age, address and national identity number. The initial of the family name and the full first name was recorded. This was a common tradition in Mongolia introduced during the communist period, as there was an effort to promote a collective identity and reduce any individualistic tendencies. In addition, a Mongolian would take their fathers name as their family name; therefore there were only shared names between siblings in the family and no others. A photograph was also taken of all participants and attached to the study forms.

Masking:
All participants were first screened for glaucoma with direct ophthalmoscopy (Vista 20 ophthalmoscope, Keeler Ltd [UK]) and optic disc photographs of both eyes were taken with a

non-mydriatic fundus camera (Canon CR4-45NM [Japan]) before screening intervention. There was no attempt to mask the participant to assignment to the screening intervention or treatment when required.

Ascertainment of outcome at follow up was designed to be based on the objective grading of optic discs and visual fields, where graders would be masked to the allocated status of the participant. A local ophthalmologist assessed the presence and patency of a Laser Peripheral Iridotomy (LPI) at follow up while gonioscopy was undertaken by a separate ophthalmologist masked to the allocation status of the participant and the presence of a Peripheral Iridotomy (PI).

Interventions:
Participants allocated to intervention had two screening tests on both eyes when possible:
1. Table top mounted A-scan (A-scan mode of an ultrasound biometer, Allergan-Humphrey model 820, Allergan [UK]) for central Anterior Chamber Depth (cACD) measurements of both eyes with cut off point of less than or equal to 2.53 mm. Five measurements were obtained, and the median of the three with the longest axial lengths was taken as the reading for that patient.
2. Tonopen measurement of Intra-Ocular Pressure (IOP) with greater than or equal to 24 mmHg as cut off point.

The cut off point for cACD measurement was selected based on an estimated sensitivity of 77% and specificity of 83%. The cut off point for IOP measurement was based on a mean plus two standard deviations for the tonopen, using data collected from a random sample of 769 Mongolians.

All participants who failed either screening criteria with one eye was referred for a full slitlamp examination. In addition, participants considered to have abnormal or glaucomatous optics discs also underwent full slitlamp examination. Those diagnosed with occludable angles on gonioscopy were then advised to have bilateral Yag PI. Participants diagnosed with glaucoma were managed appropriately with the local ophthalmologists.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Five year incidence of primary angle closure glaucoma (at design stage). Due to a delay in starting field work for follow up study, the final primary outcome was six year incidence of primary angle closure glaucoma.

Key secondary outcome(s)
Mortality

Completion date
01/10/2005

Eligibility

Key inclusion criteria

1. Aged 50 years or over
2. Living in three selected districts of Ulaan Baatar (Sukbaatar, Bayanzurkh and Chingltei) and Bayanhongor at time of recruitment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participants diagnosed with glaucoma
2. Those who were not permanent residents in the selected areas

Date of first enrolment
01/03/1999

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
United Kingdom

England

Mongolia

Study participating centre
International Centre for Eye Health
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
International Centre for Eye Health (UK)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Christian Blind Mission International

Funder Name
British Council for Prevention of Blindness

Alternative Name(s)
BCPB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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	01/11/2010		Yes	No
Protocol article	protocol	01/03/2003		Yes	No