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Evaluating the socioeconomic impact of cataract surgery for elderly patients in China

Submission date 19/12/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/01/2017	**Overall study status** Completed	
Last Edited 23/12/2016	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Cataracts are cloudy areas on the lens of the eye. They can appear for a number of reasons however they are most common in older people, developing over a long period of time (senile cataract). The lens sits near the front of the eye, and plays an important role in vision. When cataracts cause the lens to become clouded, it can prevent light from reaching the back of the eye (retina) to form an image that can be interpreted by the brain. When this happens, vision becomes blurred and distorted, and can eventually lead to blindness. In many cases, the only effective treatment is to undergo cataract surgery, which involves removing the affected lens and replacing it with a clear artificial one (intraocular lens). Un-operated cataract remains the leading cause of blindness in China, and China's cataract surgical rate (CSR) of 1000/million/year is lower than that of neighboring countries such as Vietnam (2000) and India (5500). This problem is particularly bad in rural (countryside) areas. The aim of this study is to investigate the socioeconomic (social and financial) impact of receiving free cataract surgery.

Who can participate?
Adults aged 40 years and over living in Handan County, China with poor vision in one eye due to cataracts that have not been operated on.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive cataract surgery immediately. Those in the second group are placed on a waiting list to receive cataract surgery a year later. At the start of the study and then after one year, participants in both groups complete a number of questionnaires designed to measure their household income, whether they are working and their wellbeing.

What are the possible benefits and risks of participating?
Participants who receive the surgery immediately will benefit from an improved ability to see clearly. There are no notable risks involved with participating other than the general risks of undergoing eye surgery.

Where is the study run from?
Shaanxi Normal University (China)

When is the study starting and how long is it expected to run for?
September 2016 to January 2018

Who is funding the study?
Stanford University (USA)

Who is the main contact?
Mr Matthew Boswell

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
39156

Study information

Scientific Title
Socioeconomic Impact of Cataract Surgery for Elderly Patients in China: Results from a Randomized Trial

Acronym
Handan Cataracts Study

Study objectives
The aim of this study is to measure the impact of cataract surgery on key household socioeconomic outcomes such as income and labor market participation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cataracts

Interventions
Participants are randomised to one of two groups based on baseline characteristics.

Intervention group: Participants undergo cataract surgery in February 2017. This involves small incision manual cataract surgery performed by an experienced surgeon with insertion of an appropriate intra-ocular lens, power to be determined in standard fashion by measurement of corneal curvature, axial length and refractive power in the operative and non-operative eyes.

Control group: Participants are placed on a wait-list and receive their cataract surgery in February 2018 after the collection of the final outcome measures.

Participants in both groups are followed up in standard fashion by an ophthalmologist from Tongren Hospital and complete follow up surveys after one year.

Intervention Type

Primary outcome(s)
1. Household income is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months
2. Household member time allocation is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months
3. Household member labor market participation is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months

Key secondary outcome(s))
1. Household member educational outcomes are measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months
2. Household member subjective wellbeing is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months

Completion date
30/01/2018

Eligibility

Key inclusion criteria
1. LogMAR vision ≥ 0.5 in the better-seeing eye due to un- operated cataract identified in the original Handan Eye Study (2012)

2. Resident of Handan County, China
3. Aged 40 years and over

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unwilling to give consent or unable to be contacted
2. Other ocular or health conditions that contraindicate or prevent the patient from undergoing cataract surgery

Date of first enrolment
30/01/2017

Date of final enrolment
02/07/2017

Locations

Countries of recruitment
China

Study participating centre
Shaanxi Normal University
Shaanxi
Xi'an
China
710119

Sponsor information

Organisation
Stanford University

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
University/education

Funder Name
Stanford University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Matthew Boswell (boswell@stanford.edu)

IPD sharing plan summary
Available on request