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# Northern Finland Birth Cohort eye study

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 20/09/2013 | Recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 04/10/2013 | Ongoing | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/02/2021 | Eye Diseases | |

**Plain English summary of protocol**

Background and study aims
Glaucoma is a group of eye conditions in which the optic (eye) nerve is damaged due to changes in eye pressure. Although glaucoma is treatable, it is a major cause of blindness worldwide. The objective is to study the effects of screening for eye diseases on the individuals and on society.

Who can participate?
Members of the Northern Finland Birth Cohort, born 1966.

What does the study involve?
The patients are randomly allocated to either the screening group or the no screening group. They are screened for eye diseases mainly glaucoma, with ocular imaging [visual field examinations, sharpness of vision and eye pressure measurements]. The effect of screening will be compared with no screening.

What are the possible benefits and risks of participating?
The main benefit is timely diagnosis of glaucoma, therefore avoiding the possible damage to eyesight due to the progression of glaucoma. All the investigations are non-invasive and generally well-tolerated by patients. Rarely, some people may experience mild and passing discomfort due to the dilatation of pupils.

Where is the study run from?
Oulu University Hospital, Finland.

When is the study starting and how long is it expected to run for?
The study started in April 2012 and is expected to run for 16 years.

Who is funding the study?
Silmäsäätiö, Finland.

Who is the main contact?
Ville Saarela

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Ville Saarela

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# Additional identifiers

**Protocol serial number**
71016

# Study information

**Scientific Title**
Northern Finland Birth Cohort eye study: a randomised screening trial

**Study objectives**
Evaluation of the effectiveness and cost effectiveness of glaucoma screening.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Northern Ostrobothnia Hospital district, Finland

**Primary study design**
Interventional

**Study design**
1. Randomised screening trial
2. Diagnostic cohort study
3. Cost-effectiveness trial and cohort study

**Study type(s)**
Screening

**Health condition(s) or problem(s) studied**
Glaucoma

**Interventions**

Screening for eye diseases, mainly glaucoma, with ocular imaging (scanning laser polarimetry, optical coherence tomography, retinal nerve fibre layer photography, scanning laser ophthalmoscopy, stereoscopic optic nerve head photography)
2. Visual field examinations
3. Visual acuity and intraocular pressure.
The patients are randomised with respect to age, gender and area of residence. The effect of screening will be compared with no screening after 16 years.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
The clinical evaluation of glaucomatous damage in the visual fields, optic nerve head and retinal nerve fibre layer will be compared with the group with screening and those without screening, after 16 years

### Key secondary outcome(s)
Effectiveness and cost-effectiveness

### Completion date
31/12/2028

## Eligibility

### Key inclusion criteria
Randomized members of Northern Finland Birth Cohort (born in 1966 in the two northernmost provinces in Finland)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
10321

### Key exclusion criteria
Those who are not a part of Northern Finland Birth Cohort

**Date of first enrolment**
01/04/2012

**Date of final enrolment**
31/12/2028

# Locations

**Countries of recruitment**
Finland

**Study participating centre**
**Department of Ophthalmology**
Oulu
Finland
90029

# Sponsor information

**Organisation**
Silmäsäätiö (Finland)

**ROR**
https://ror.org/033r0hh63

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Silmäsäätiö (Finland)

# 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 | glaucoma prevalence results | 01/03/2019 | 12/02/2021 | Yes | No |
| Protocol article | protocol | 08/10/2013 | 12/02/2021 | Yes | No |