

Northern Finland Birth Cohort eye study

Submission date 20/09/2013	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/10/2013	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/02/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

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

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Contact details

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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

Study design

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

Primary study design

Interventional

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