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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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
Effectiveness and cost-effectiveness

Overall study start date
01/04/2012

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

Age group
Adult

Sex
Both

Target number of participants
3350

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)

Sponsor details
Mannerheimintie 136 A 28
Helsinki
Finland
00270

Sponsor type
Research organisation

Website
http://www.silmasaatio.fi/

ROR
https://ror.org/033r0hh63

Funder(s)

Funder type
Research organisation

Funder Name
Silmäsäätiö (Finland)

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