

Nitric Oxide Biomarkers in Glaucoma and Tinnitus

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|------------------------------|----------------------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Glaucoma and ocular hypertension |
| Study type | Observational invasive |

Summary

ID

NL-OMON49687

Source

ToetsingOnline

Brief title

NO biomarkers

Condition

- Glaucoma and ocular hypertension

Synonym

Glaucoma; POAG

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W, European committee and Uitzicht

Intervention

Keyword: Glaucoma, Nitric Oxide, Tinnitus

Outcome measures

Primary outcome

Concentrations of amino acids which mark nitric oxide production in glaucoma patients both with and without tinnitus.

Secondary outcome

N/A

Study description

Background summary

Low nitric oxide (NO) bioavailability and oxidative stress may be common mechanisms behind glaucoma and tinnitus. NO itself diffuses quickly and is difficult to measure, however, certain metabolites can be measured as biomarkers of NO production.

Study objective

The aim of this study was to test these biomarkers of NO in glaucoma patients both with and without tinnitus. The objective was also to replicate findings from a previous study performed in Amsterdam, a collaboration between our research group and the AMC

Study design

Observational, cross-sectional

Study burden and risks

Patients who are already scheduled for an appointment in the ophthalmology clinic and who agree to participate will then be asked to go to the blood draw clinic after their appointment. Glaucoma patients will not perform any ophthalmological tests in relation to this study. The blood draw may cause minimal discomfort or bruising, but is a routine procedure. Patients will

require a maximum of 30 minutes for the blood draw. Healthy controls who send signed informed consent will be asked to go to the ophthalmology clinic for screening tests, and then afterwards to get the blood draw. If abnormal eye screening results are obtained for healthy subjects, they will be referred to their GP. Detection of signs of glaucoma may cause psychological stress, however, an early diagnosis will allow treatments to be initiated and therefore more preservation of visual functioning. Glaucoma patients will not perform any ophthalmological screening tests; therefore there is no risk of identifying any other eye conditions. Overall the study causes minimal discomfort and risk to the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

50-70 years of age

For patients only: Diagnosed primary open angle glaucoma

For those with tinnitus, response of tinnitus **always** or **sometimes** in F1 questionnaire

Written informed consent.

Exclusion criteria

Patients taking ototoxic medications will be excluded from this study. These include: loop diuretics, Aspirin, NSAIDs, and chemotherapy agents.

For healthy controls only, glaucoma or family history of glaucoma. This will be determined by the ophthalmologic screening described in section 3.

Study design

Design

| | |
|---------------------|---------------------------------|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

Primary purpose: Basic science

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-08-2020 |
| Enrollment: | 40 |
| Type: | Actual |

Ethics review

Approved WMO

| | |
|--------------------|---|
| Date: | 15-04-2020 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL72776.042.20 |