Zinc and AMD.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22306

Source
NTR

Health condition

AMD, complement, zinc

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
P.O. Box 9101, 6500 HB Nijmegen
The Netherlands
Source(s) of monetary or material Support: Non-commercial research
Radboud University Nijmegen Medical Centre

Intervention

Outcome measures

Primary outcome

The primary outcome is the serum level of activation fragment C3d and complement component C3. The C3d/C3 ratio will be calculated. This ratio is the activity marker of the alternative complement pathway.

Secondary outcome

The secondary outcome is the correlation between this supposed drop in serum level C3 en

C3d and Y402H polymorphism status in CFH.

Study description

Background summary

Rationale:

Zinc and antioxidants supplementation can delay the progression of age-related macular degeneration (AMD). Compared to controls, AMD patients have a higher level of complement-mediated inflammation as demonstrated by subretinal complement deposits (drusen). The AREDS study has demonstrated that zinc supplementation may prevent the progression of AMD and preserve visual function in 21 % of patients. In addition, it has been demonstrated that zinc has the ability to temper activation of the complement cascade by direct binding to active complement molecules.

Objective:

1. To determine if zinc supplementation in AMD patients has a direct measurable effect on the complement system explaining the mechanism through which this substance exerts its influence on AMD progression;

2. To determine whether this proposed effect of zinc is influenced by the genetic status, regarding the Y402H and ARMS2 polymorphism, enabling us to identify subgroups of patients more susceptible to the beneficiary effect of zinc.

Study design:

80 AMD patients will be enrolled. These groups will receive 50 mg oral zinc supplements during 3 months. Serum level of complement component C3 and activation fragments C3d will be analyzed prior, during and post treatment.

Study population:

80 AMD patients of 50 years of age or older with extensive small, intermediate, and large drusen, geographic atrophy and/or exudative AMD but without active disease as demonstrated by active neovascularisation, will be recruited for the study.

Intervention:

All participants of the study will receive daily oral 50 mg zinc as zinc sulfate and 1 mg copper as cupric sulphate for 3 months. The reason for the presence of a small amount of copper is based on the fact that zinc and copper compete for the same membrane transport systems. The ratio zinc to copper in the present preparation reflects the physiological situation. The same reasoning has also been followed in the Age-Related Eye Disease Study (AREDS) of the National Institutes of Health in the US.

Study objective

To determine if zinc supplementation in AMD patients has a direct measurable effect on the complement system explaining the mechanism through which this substance exerts its influence on AMD progression.

Study design

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Intervention

All participants of the study will receive oral 50 mg zinc as zinc sulfate and 1 mg copper as cupric sulphate dailly for 3 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Men and women ≥ 50 years of age;

2. AMD patients previously included in the EUGENDA database;

3. Previously genotyped for Y402H (rs1061170) gene variation (from EUGENDA database);

4. Patients with extensive small drusen, intermediate drusen, large drusen, advanced neovascular AMD without neovascular activity in one or both eyes or geographic atropy in one or both eyes;

5. Informed consent.

Exclusion criteria

1. Active leakage from CNV due to AMD;

2. Ongoing anti/VEGF treatment;

3. Ongoing infection;

4. Subretinal hemorrhages;

5. History of any vitreous hemorrage within 12 weeks;

6. Other ocular disorders that may confound the interpretation of the study results;

7. Systemic or local steroid treatment within the last three months;

8. Use of any antibiotica;

9. Prolonged use of diuretics;

10. Supplemental use of iron (38-65 mg/day of elemental iron);

11. Use of zink and vitamin supplements one month prior to the study;

12. Systemic diseases that may influence complement levels (atypical haemolytic uraemic syndrome (aHUS), membranoproliferative glomerulonephritis type 2 (MG2)).

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35087
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2488
NTR-old	NTR2605
CCMO	NL31655.091.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35087

Study results

Summary results
N/A