Zinc and AMD.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22306

Bron
NTR

Aandoening

AMD, complement, zinc

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
P.O. Box 9101, 6500 HB Nijmegen
The Netherlands
Overige ondersteuning: Non-commercial research
Radboud University Nijmegen Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Serum level of complement component C3 and activation fragments C3d will be analyzed prior, during and post treatment.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-06-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-11-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35087
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A