Effects of folic acid on the human microcirculation: a randomized, doubleblind, placebo-controlled study.

Gepubliceerd: 19-10-2006 Laatst bijgewerkt: 18-08-2022

Folate supplementation improves microcirculatory function in subjects susceptible to microcirculatory dysfunction.

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

Samenvatting

ID

NL-OMON23261

Bron
Nationaal Trial Register

Verkorte titel
N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Endothelium-dependent and endothelium-independent skin blood flow using laser-doppler fluxmetry combined with iontophoresis;
2. nailfold video capillaroscopy.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Folates may have beneficial effects on cardiovascular risk.
Firstly, folate status is an important determinant of plasma homocysteine concentration, which is associated with an increased risk of cardiovascular disease (CVD). Moreover, epidemiologic studies have identified an association between folate status and CVD that is statistically independent of homocysteine. Folate has also been linked to hypertension and insulin resistance.

Thus, the association between folate and CVD may be explained both by direct effects of folate on the vessel wall, as well as by indirect effects, including detrimental effects on blood pressure and insulin sensitivity. Intervention trials using folates, mostly in secondary prevention settings, are yet inconclusive with regard to cardiovascular morbidity and mortality.
As an alternative to clinical endpoint studies, the effects of folates on the vascular system may be studied using surrogate endpoints. One of these surrogate endpoints is microcirculatory function. The prognostic value of microcirculatory dysfunction for clinical cardiovascular endpoints remains to be established. However, several risk factors for CVD are correlated to microcirculatory function, such as hypertension, insulin resistance and obesity.

No previous studies have addressed the question of whether folate supplementation influences the human microcirculation.

Doel van het onderzoek

Folate supplementation improves microcirculatory function in subjects susceptible to microcirculatory dysfunction.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. Folic acid 0,5 mg daily during 8 weeks;

2. 5-methyltetrahydrofolate 5 mg once.

Contactpersonen

Publiek

Y.M. Smulders

Amsterdam
The Netherlands

Wetenschappelijk

Y.M. Smulders
Amsterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: 25-55;

2. BMI > 25 and BMI < 30;

3. causcasian.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medication affecting cardiovascular function;

2. systolic bloodpressure > 160;

3. diastolic bloodpressure > 95;

4. diabetes mellitus;

5. anemia;

6. renal insufficiency.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2006
Aantal proefpersonen:	58
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-10-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL795

Register	ID
NTR-old	NTR808
Ander register	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A