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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23261

Source
Nationaal Trial Register

Brief title
N/A

Intervention

Outcome measures

Primary outcome

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

2. nailfold video capillaroscopy.

Secondary outcome

1. (Ambulatory) blood pressure;

2. vascular resistance;

3. cardiac output.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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

2. 5-methyltetrahydrofolate 5 mg once.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age: 25-55;

2. BMI > 25 and BMI < 30;

3. causcasian.

Exclusion criteria

1. Medication affecting cardiovascular function;

2. systolic bloodpressure > 160;

3. diastolic bloodpressure > 95;

4. diabetes mellitus;

5. anemia;

6. renal insufficiency.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	58
Type:	Actual

Ethics review

Positive opinion

Date:	19-10-2006
Application type:	First submission

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
NTR-new	NL795

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

Study results

Summary results
N/A