Effects of low-dose aspirin taken at bedtime on hypertension

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

Samenvatting

ID

NL-OMON25788

Bron
NTR

Verkorte titel
ASPIRETENSION study

Aandoening

Hypertension, aspirin, renin-angiotensin-aldosterone system

Hypertensie, aspirine, renine-angiotensine-aldosteronsysteem

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Vascular Medicine Unit
Department of General Internal Medicine and Endocrinology
Overige ondersteuning: Leiden University Medical Center
Vascular Medicine Unit
Department of General Internal Medicine and Endocrinology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Renin-angiontensin-aldosterone system represented by renin activity

Toelichting onderzoek

Achtergrond van het onderzoek

Aspirin is a potent vasoprotective drug, widely used in secondary prevention of cardiovascular events. Until recently, it was thought not have any influence on tension. However, in some recent studies, 100mg aspirin, administered at bedtime and not upon awakening, showed to decrease blood pressure significantly, although underlying mechanisms are unclear. Therefore, in this study we will examine through which mechanisms aspirin 100mg at bedtime could have supplementary benefit to patients with hypertension by reducing their tension.
We hypothesise that aspirin 100mg at bedtime decreases tension by nocturnally lessening increase of the renin-angiotensin-aldosterone system, enhancing NO bioavailability, lessening autonomous nervous system activity and inhibiting COX-1 dependent thromboxane A2 production. Our objectives are to examine effects of aspirin 100mg at bedtime on these mechanisms.
The trial will have a prospective, randomised, placebo controlled, double blind and crossover study design.
We will use 15 subjects with grade 1 essential hypertension (140/90-159/99 mmHg). Patients with more severe hypertension will be excluded, as well as them with secondary hypertension, personal history of cardiovascular events, diabetes mellitus, rheumatoid arthritis, vasoactive medication or any contraindication to use of aspirin.
After patient’s written informed consent and screening, subjects will be randomised between aspirin at awakening and at bedtime in two treatment periods of 2 weeks. They will also get a placebo for respectively evening and morning to achieve full blinding. Between treatment periods, there will be a washout period of 4 weeks.
Before both periods there will be a short visit of half an hour to our centre and after both periods there will be an admission for 24 hours to the research centre of general internal medicine. With regular intervals blood will be sampled, 24 hours urine will be collected, tension will be measured and also some other non-invasive experiments will be done.

Doel van het onderzoek

We hypothesise that aspirin 100mg at bedtime decreases tension by nocturnally lessening increase of the renin-angiotensin-aldosterone system, enhancing NO bioavailability, lessening autonomous nervous system activity or inhibiting COX-1 dependent thromboxane A2 production. Our objectives are to examine effects of aspirin 100mg at bedtime on these mechanisms.

Onderzoeksopzet

Before both 2-week periods there will be a short visit of half an hour to our centre and after both periods there will be an admission for 24 hours to the research centre of general internal medicine. With regular intervals blood will be sampled, 24 hours urine will be collected, tension will be measured and also some other non-invasive experiments will be done.

Onderzoeksproduct en/of interventie

After patient’s written informed consent and screening, subjects will be randomised between 100 mg aspirin at awakening and at bedtime in two treatment periods of 2 weeks. They will also get a placebo for respectively evening and morning to achieve full blinding. Between treatment periods, there will be a washout period of 4 weeks.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Essential hypertension, without treatment <160/100 mm Hg, with treatment <140/90 mm Hg. If treated, treatment should be stopped before entering into study.

2. Age 18-80 year

3. Capacity to give informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Moderate or severe hypertension (>160/100)

2. Secondary hypertension

3. Personal history of cardiovascular events

4. Diabetes mellitus

5. Rheumatoid arthritis

6. Vasoactive medication

7. Any contraindication to use of aspirin

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2007
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-03-2008
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	NL1162
NTR-old	NTR1206
Ander register	Medical Ethics Committee Leiden University Medical Center : MEC P06.063
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A