Effects of low-dose aspirin taken at bedtime on hypertension

No registrations found.

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

Summary

ID

NL-OMON25788

Source
NTR

Brief title
ASPIRETENSION study

Health condition

Hypertension, aspirin, renin-angiotensin-aldosterone system

Hypertensie, aspirine, renine-angiotensine-aldosteronsysteem

Sponsors and support

Primary sponsor: Leiden University Medical Center
Vascular Medicine Unit
Department of General Internal Medicine and Endocrinology
Source(s) of monetary or material Support: Leiden University Medical Center
Vascular Medicine Unit
Department of General Internal Medicine and Endocrinology

Intervention

Outcome measures

Primary outcome

Renin-angiontensin-aldosterone system represented by renin activity

Secondary outcome

Secondary endpoints are other determinants of RAAS-activity, markers of autonomous nervous system activity, COX-inhibition, vascular wall inflammation, vascular adhesion molecules and coagulation. We also measure 24-h blood pressure as well as central arterial stiffness (by non-invasive pulse wave analysis) to determine whether blood pressure effects are more centrally or peripherally located.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2007
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

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

Study results

Summary results

N/A