Effects of low-dose aspirin taken at bedtime on pathophysiologic mechanisms underlying hypertension in subjects with grade 1 essential hypertension: the Aspirin In Reduction of Tension (ASPIRETENSION) study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON29702

Source
ToetsingOnline

Brief title
ASPIRETENSION study

Condition

- Other condition

Synonym
hypertension

Health condition

hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Viatris

Intervention

Keyword: aspirin, hypertension, pathophysiologic mechanisms

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

Cardiovascular events are the leading cause of mortality and morbidity at present. One of the most important risk factors is hypertension and unless the existence of many antihypertensive agents, lots of patients maintain an uncontrolled tension.
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.

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 and inhibiting COX-1 dependent thromboxane A2 production. Our objectives are to examine effects of aspirin 100mg at bedtime on these mechanisms.

Study design

The trial will have a prospective, randomised, placebo controlled, double blind and crossover study design.

Intervention

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 burden and risks

Totally, the study will have a duration of 8 weeks. Patients will take pills for 4 weeks. The most important burden consists of two admissions of 24 hours to our research center.
Risks are very low. Mostly described adverse effects of aspirin are formed by a somewhat higher risk for bleeding, particularly in the gastrointestinal tract, but our dosage and length of intervention minimalise this risk. Patients with a history of gastrointestinal ulcus or bleeding will be excuded from participation, as will patients with asthma, because aspirin could provoke excacerbations of this disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Essential hypertension, without treatment <160/100 mm Hg, with treatment <140/90 mm Hg. If treated, treatment should be stopped before entering into study.
-Age 18-80 year
-Capacity to give informed consent

Exclusion criteria

-Moderate or severe hypertension (>160/100)
-Secondary hypertension
-Personal history of cardiovascular events
-Diabetes mellitus

-Rheumatoid arthritis
-Vasoactive medication
-Any contraindication to use of aspirin

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2007
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ascal
Generic name:	Carbasalate Calcium
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	12-04-2006
Application type:	First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2006-001359-36-NL
CCMO	NL11833.058.06