Adenosine Measurement in humans in vivo

Published: 02-05-2007
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Creating a reproducible and valid method for adenosine measurement

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON31238

Source
ToetsingOnline

Brief title
Adenosine Measurement in humans in vivo

Condition

- Myocardial disorders
- Ancillary infectious topics

Synonym
niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMW subsidie BPC Ramakers (AGIKO)

Intervention

Keyword: adenosine, blocker-solution, cold pressor test, dipyridamol

Outcome measures

Primary outcome

Adenosine concentrations

Secondary outcome

forearm bloodflow (vasodilatation/vasoconstriction)

Study description

Background summary

Adenosine, a degradation product of adenosinetriphosphate (ATP) accumulates in many tissues following hypoxia, ischemia and inflammation. Known as the *retaliatory* metabolite adenosine is able to modulate several physological processes.

Adenosine is formed both extracellular as intracellular by dephosphorylation of adenosinemonophosphate (AMP) by 5*-nucleotidase. The degradation of adenosine is mainly intracellular, through adenosine deaminase and adenosine kinase. The equilibrative nucleoside transporter (ENT) controles facillitated diffusion between extra- and intracellular adensoine.

Over the past 60 years adenosine measurement has proven to be an extremely difficult task. With a half life of approximately 1 second adenosine is rapidly taken up and metabolised by erythrocytes.

In this study we describe an optimized method for the detection of adenosine in blood. First, a syringe system enables us to withdraw blood and deliver blocker solution to the sample at the same time. Secondly, a blocker solution consisting of an adenosine re-uptake inhibitor, deaminase inhibitor, kinase inhibitor and a 5`-nucleotidase inhibitor, paralyses the adenosine metabolism.

In order to create a reproducable and valid method for adenosine measurement we tested blood several times within the same subject. Furthermore we used the cold pressor test (CPT) as a local vasoconstrictor-inducing stimulus to increase plasma levels of adenosine. Treatment with the well-known adenosine re-uptake inhibitor dipyridamole was used to create higher levels of plasma adenosine.

Study objective

Creating a reproducible and valid method for adenosine measurement

Study design

methodological

Intervention

Cold Pressor test:
The volunteers left hand will be held in ice water for 2 minutes

Forearm Bloodflow will be measured by venous occlusion plethysmography.

Study burden and risks

Time: screening 20 minutes
experiments day 1 and 7: 210 minutes

Bloodsampling: venous infusion on day 1 and 7 in both arms

Bloedcollection: total bloodsampling 50 ml.

Dipyridamole: Subjects will use dipyridamole for 7 days (twice daily Persantin retard 200 mg). The *safety-analysis* ESPS-2 study showed that this concentration is safe, besides a headache no other adverse effects are to be expected. There are no health riks involved in the use of dipyridamole.

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

No medical history
No medication
age 18-35 years
non-smokers

Exclusion criteria

medical history
hypertension

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-06-2007
Enrollment:	17
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Persantin
Generic name:	Dipyridamole
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	02-05-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2007-001930-15-NL
CCMO	NL17446.091.07