Adenosine measurement in humans in vivo

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1. Creating a reproducible and valid method for adenosine measurement2. Studying the effect of dipyridamole on the endogenous adenosine concentration before and after CPT.

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

Summary

ID

NL-OMON34657

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, dipyridamole

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

1. Creating a reproducible and valid method for adenosine measurement
2. Studying the effect of dipyridamole on the endogenous adenosine concentration before and after CPT.

Study design

methodological

Intervention

Cold Pressor test:
The volunteers non-dominant 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 the non-dominant arm
Bloedcollection: total bloodsampling 50 ml.
Dipyridamole: Subjects will use dipyrid amole 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:	Recruitment stopped

Start date (anticipated):	01-05-2010
Enrollment:	28
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:	16-03-2010
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	NL31478.091.10