The effects of an active versus an inactive lifestyle on the renal function during exercise and dehydration

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The primary objective of this study is to examine if the respones of the kidneys to exercise and dehydration are different between healthy active and inactive males.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42643

Source
ToetsingOnline

Brief title
Renal function during exercise and dehydration

Condition

- Other condition

Synonym
Dehydration

Health condition

Inspannings gerelateerde gezondheidsrisico's

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: STW

Intervention

Keyword: Dehydration, Exercise, Physical activity level in daily life, Renal function

Outcome measures

Primary outcome

The primary outcome parameters of this study are the estimated glomerular filtration rate, the plasma copeptide concentration and the plasma renin activity.

Secondary outcome

Secondary study parameters/endpoints (if applicable)

• Serum and urine creatinine concentration (as a measure for renal clearance)

• Plasma and urine osmolarity (as a measure for fluid balance and urine concentrating ability)

• Plasma and urine sodium concentration (as a measure for the fluid balance)

• Urine Aquaporine-2 (AQP2) concentration (as a measure for urine concentrating ability)

• Hematocrit en Hemoglobine (as markers for dehydration, which can be used to calculate plasma volume changes)

Other study parameters (if applicable)

• Hart rate (to determine the exercise intensity during the sub-maximal exercise)

• Rating of Perceived Exertion (BORG-score).

• Thermal Sensation Score.

• Plasma en urine succinate concentration (as a measure for renal stress/damage)

• Plasma en urine lactate concentration (as a measure for renal stress/damage)

• Urine glucose concentration (as a measure for renal stress/temporary proximal tubulus damage)

• Urine albumine concentration (as a measure for renal stress/damage)

• Urine Kidney Injury Molecule-1 (KIM-1) concentration (as a measure for renal stress/damage)

• Urine Neutrophil Gelatinase-Associated Lipocalin (NGAL) concentration (as a measure for renal stress/temporary distal tubulus damage)

• Urine IgG concentration (as a measure for renal stress/temporary glomerular damage)

Study description

Background summary

The renal perfusion in rest is approximately 20-25% of the cardiac output and it is of great importance for a normal functioning of the human body. An important function of the kidneys is maintaining of the water and salt homeostasis. Dehydration is the reduction of the body mass (>2%) by excessive fluid loss. Next to the negative consequences of dehydration on exercise performance, dehydration also increase the risk to develop heat-related illnesses, fatigue/exhaustion, loss of coordination and loss of consciousness. During exercise and dehydration the renal function will change. For example there is a decrease in renal perfusion, which results in a lower renal clearance of wast products. Furthermore, two mechanisms to maintain the water

and salt balance will be activated. First of all, there is an increased secretion of the arginin vasopressin (AVP), which stimulates the reabsorption of water by the kidneys. Second, the renin angiotensin aldosteron pathway become activated, resulting in a higher reabsorption of water and salt in the renal tubules. However, it is unknown if the responses to exercise and dehydration are different between healthy active males and inactive males. If the adaptaptional ability of the kidneys are different, this will give us the important new insight that exercise is good for maintaining the osmo- and fluid balance, which indicates that the renal function have benefits from exercise. A better adaptational ability of the kidneys may possibly be an advantage in other (clinical) situations and/or disturbances.

Study objective

The primary objective of this study is to examine if the respones of the kidneys to exercise and dehydration are different between healthy active and inactive males.

Study design

Observational study

Study burden and risks

During the study the subjects are exposed to two exercise test, including one maximal exercise test. Maximal exercise testing is safe and not associated with health risks. Moreover, subjects are medically screened prior to the exercise and the test location is provided with an AED and an emergency box with emergency medications. This emergency box is compiled and checked by the pharmachy of the Radboudumc. During the proposed study a blood sample will be taken four times using a vena punction. The blood sample will be used to determine the osmolarity, creatinine concentration, plasma copeptide concentration and plasma renine activity. The collection of a blood sample with a vena punction is a frequently used medical intervention without any risks, in particular because the vena punction will be performed by an experienced employee.A potential negative effect of the vena punction could be the development of a small haemorrhage. However, the incidence is low (5%), completely reversibel and not a limiting factor in daily life. Next to the blood samples, a urine sample will be collected three times during the study. The total load of these provisions, both physically and in time, are minimal provide important information necessary for answering the main question

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Philips van Leijdenlaan 15
Nijmegen 6525EX
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Philips van Leijdenlaan 15
Nijmegen 6525EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy Male (18-30 years)
Active group: activity-score >=9400.
Inactive group: activity-score <6400.

Exclusion criteria

- History of kidney disease
- Baseline estimated glomerular filtration rate <90 ml/min
- Contra-indication for performing a maximal cycling test

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-06-2015
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2015
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
CCMO	NL52731.091.15

Study results

Date completed:	01-05-2016
Actual enrolment:	36