Feasibility test of a respiratory challenge in the MRI to image the vascularity of the brain and the head and neck area.

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The primary objective is to test the feasibility of MRI measurements at 3T and 7T under dynamic hypercapnic or hyperoxic conditions controlled by digitally regulated respiratory challenges in volunteers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON41270

Source
ToetsingOnline

Brief title
MRI with RespirAct

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Central nervous system vascular disorders

Synonym
head and neck cancer, Vascular disease of the brain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Arterial spin labeling MRI, BOLD-MRI, Dynamic carbon dioxide and oxygen enhancement MRI, Respiratory challenge

Outcome measures

Primary outcome

The primary study parameter is the feasibility of MRI measurements at 3T and 7T

under dynamic hypercapnic or hyperoxic conditions.

Secondary outcome

Control values of vascular reactivity and oxygenation status in brain and head

and neck region.

Study description

Background summary

Respiratory challenges are used to assess the reactivity of the brain vasculature to CO2 and O2 or to estimate the reactivity and oxygenation status of a tumor. The reactivity of brain vasculature is a measure for the severity of vascular brain diseases. In tumors, the reactivity is a measure of the maturity of the vasculature and, thereby, of the level of malignancy. Moreover, the reactivity of the vasculature shows the possibilities for improvement of the oxygenation during therapy. Further, respiratory challenges can be used to calibrate Blood Oxygen Level Dependent (BOLD) and Arterial Spin Labelling (ASL) MRI.
In dynamic CO2 and O2 enhanced MRI, a robust and repeatable challenge is required to reliably correlate the challenge with the changes in blood flow and blood oxygenation of the tumour. These respiratory challenges will be controlled by a gas blender, the RespirAct, which modulates inspiration of O2 and CO2 to achieve a reliable and repeatable gas delivery and thereby arterial blood gasses. The measurements will be performed at 3T and 7T. At 3T a lot of experience is developed with brain reactivity measurements with MRI and functional MRI of head and neck tumors. Since the availability of 3T scanners is high, the tests might be easier repeated in other hospitals. At 7T, the magnitude of expected changes will be larger. Therefore, more subtle changes

might appear on a 7T measurement.

Study objective

The primary objective is to test the feasibility of MRI measurements at 3T and 7T under dynamic hypercapnic or hyperoxic conditions controlled by digitally regulated respiratory challenges in volunteers.

Study design

This is a pilot study that will test the feasibility of the application of, first, a respiratory challenge and, second, a respiratory challenge during an MRI measurement at 3T or 7T. Several existing MRI techniques will be optimized to measure the effect of the respiratory challenge. MRI techniques applied are designed to measure the level of deoxygenated blood (BOLD), the amount of dissolved molecular O2 (T1), the blood perfusion (ASL), the blood vessel index (VSI) and the pH (Chemical Exchange Saturation Transfer (CEST)).

Study burden and risks

The controlled gas breathing requires a closed breathing system. Therefore, subjects have to breathe through a mask. Further, CO2 end-tidal levels of 45-60 mmHg (baseline + 20 mmHg) can induce an increased breathing frequency due to physiological stress. However, end-tidal levels of 30-60 mmHg CO2 are in physiological ranges and are experienced repeatedly my most people over the day. If patients experience discomfort because of high arterial CO2 levels, they can open a valve in the mask or squeeze the panic button in the MRI and the researcher can switch immediately to 100% oxygen by pushing the red button on the front of the gas blender.

The safety of the RespirAct is guaranteed by the following features of the gas blender and the actions that are taken:
- The minimum O2 level in all the gas mixtures is 10%.
- CO2 and O2 levels and breathing frequency is monitored constantly online.
- An independent blood oxygen saturation and respiratory rate monitoring will be performed during the MRI measurements with fingertip pulse oximetry and a pressure sensor for the respiratory rate.
- Everyone who will operate the RespirAct will be trained and certified by the manufacturer.

Subjects will not benefit from the respiratory challenge with or without combination with MRI.
Only one visit will be required for the brain measurements. For head and neck measurements, the subject will be asked to participate for minimum 3 and maximum 6 separate MRI sessions, besides the application of the custom-made mask.

No risks are known for undergoing an MRI.

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

- Informed consent
- 18 years or older

Exclusion criteria

- Unwilling or unable to co-operate with breathing manoeuvres
- Respiratory or cardiac limitations to breathing at 20 L/min

- Medical contra-indications to limited hypercapnia or hypocapnia (known increased intracerebral pressure, metabolic acidosis or alkalosis)
- Brain or head and neck tumour
- Vascular disease of the brain
- Altered consciousness
- Standard contraindications for 3T or 7T MRI scanning
- Non compliance with prescribed anti-seizure medication
- Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2013
Enrollment:	145
Type:	Actual

Ethics review

Approved WMO Date:	09-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-09-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	26-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL38462.041.11