Interindividual differences in stress sensitivity during MR-guided prostate biopsy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Genitourinary tract disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON42574

Source
ToetsingOnline

Brief title
Stress-biopsy

Condition

- Genitourinary tract disorders NEC

Synonym
prostate cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biopsy, MRI, prostate cancer, stress sensitivity

Outcome measures

Primary outcome

The primary objective of our study is to measure individual stress reactivity by means of self-assessment and cortisol changes in patients during MR-guided prostate biopsy.

Secondary outcome

The subjective and physiological stress response while undergoing the diagnostic intervention will be associated to potential predictive markers in personality characteristics, habitual stress levels, coping abilities and stress-related brain connectivity patterns. Brain connectivity measures related to stress response, such as the interplay between the human salience and executive control networks [13], stress coping abilities, depression, anxiety, psychological burden and long term stress exposure may constitute vulnerability or resilience factors in relation to the peri-interventional stress response.

Study description

Background summary

Prostate cancer (PCa) is the most diagnosed non-skin cancer in men in the Netherlands. Population aging and wider spread use of prostate-specific antigen (PSA) screening tests are expected to further increase diagnosis of this disease. In case of an elevated PSA, systematic transrectal ultrasound (TRUS)-guided prostate biopsy is currently the standard technique to detect PCa. However, as PSA is a non-specific marker for prostate cancer, urologists are increasingly confronted with the dilemma of seeing patients with a high clinical suspicion of PCa but negative initial TRUS-guided biopsy results. More

recently, the use of multi-parametric MR imaging has been well established in detecting PCa, showing high localization accuracy. Consequently, MR imaging has also been proposed in guiding biopsies towards cancer suspicious regions, with the aim of improving diagnostic performance. MR-guided prostate biopsy is routinely used in clinical practice at this institution Although MR imaging is generally regarded as a safe diagnostic procedure, admission to the MR machine in itself is a potential stressor, which coupled with the biopsy and threat of cancer, may give rise to a strongly aversive and stressful subjective experience.

Study objective

The purpose of our study is to assess the subjective stress response during MR guided prostate biopsy and elucidate potential mediating influences of cognitive and affective factors, long term stress exposure and stress-related brain connectivity dynamics.

Study design

Prospective, non-randomized, single centre exploratory study. Within 2-3 days prior to their medical intervention subjects will fill in 5 questionnaires about their emotional well-being (~30 min) and one sheet about their medical history. Prior to the biopsy they will get a 15 min. scan of the brain and saliva and hair cortisol will be sampled, along with subjective ratings of the affective state.

Study burden and risks

The routine clinical practice at the day of the intervention will be extended by an additional MRI for which the patients will have to lie in a different position. There are no elevated risks related to the additional MRI sequences or the sampling of the saliva/hair or filling in of the questionnaires at home.

Contacts

Public
Radboud Universitair Medisch Centrum

Reinier Postlaan 10
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Reinier Postlaan 10
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:;- 50 -70 years of age
- PSA * 4.0 ng/mL and/or positive digital rectal examination
- suspicious lesion (PIRADS 3 to 5) on diagnostic MR imaging examination
- Signed MRI screening form (to search for metal device/foreign bodies/claustrophobia)
- Signed IRB-approved informed consent form

Exclusion criteria

- Patients unable to undergo MR imaging, including those with contra-indications
- Contra-indications to MR-guided prostate biopsy
- Impossibility to obtain a valid informed consent
- History of psychiatric treatment or current psychiatric treatment as revealed by self report.
- History of neurological treatment or current neurological treatment as revealed by self report.
- History of endocrine treatment or current endocrine treatment as revealed by self report.
- Claustrophobia.

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):	01-09-2016
Enrollment:	51
Type:	Actual

Ethics review

Approved WMO

Date:	06-06-2016
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	NL55573.091.15