A study of non-invasive diagnostic techniques in renal osteodystrophy: 18F-sodiumfluoride positron emission tomography and serum non-oxidized PTH compared to bone histomorphometry

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To assess accuracy of 18F-sodiumfluoride (NaF) positron emission tomography (PET) and serum non-oxidized parathyroid hormone (PTH) as an accurate, reliable and easy applicable diagnostic tools for the assessment of bone turnover in chronic kidney...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON48097

Source
ToetsingOnline

Brief title
A study of non-invasive diagnostic techniques in renal osteodystrophy

Condition

- Bone disorders (excl congenital and fractures)
- Nephropathies

Synonym
renal osteodystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC, locatie VUmc
Source(s) of monetary or material Support: Amsterdam Movement Sciences

Intervention

Keyword: Biopsy, Kidney disease, PET

Outcome measures

Primary outcome

Primary endpoint is 1) the association between bone turnover as assessed with

18F-NaF PET and bone turnover as assessed by bone histomorphometry.

Secondary outcome

associations of total PTH and non-oxidized PTH with bone turnover as measured

with bone histomor-phometry; associations of bone turnover as measured with

18F-NaF PET and nonoxidized PTH measurements with conventional serum bone

turnover markers.

Study description

Background summary

Renal osteodystrophy is characterized by abnormalities in bone turnover, mineralization, and volume in the setting of chronic kidney disease. Knowledge regarding the underlying bone disorder, in particular the bone turnover rate, is essential in the treatment choice. However, current non-invasive diagnostic tests cannot discriminate accurately between high and low bone turnover. Transiliac bone biopsy is the gold standard but has limitations including being invasive, being limited to one skeletal site and requiring considerable expertise. Thus, reliable noninvasive techniques to classify bone turnover in renal osteo-dystrophy are of utmost importance.

Study objective

To assess accuracy of 18F-sodiumfluoride (NaF) positron emission tomography

(PET) and serum non-oxidized parathyroid hormone (PTH) as an accurate, reliable and easy applicable diagnostic tools for the assessment of bone turnover in chronic kidney disease (CKD) patients.

Study design

Cross-sectional study. Patients will be recruited from the outpatient clinic of nephrology in the AUMC locations AMC and VUMC.

Intervention

Non-oxidized PTH, 18F-NaF PET and other bone marker turnovers (BTMs) compared to histomorpho-metric bone biopsy as the gold standard

Study burden and risks

Sixteen patients referred to undergo a living kidney transplant will be included. Patients will undergo dual energy X-ray absorptiometry (DXA), 18F-NaF PET and fasting blood sampling to assess classical bone turnover markers and non-oxidized PTH. Transiliac bone biopsy will be performed after the transplanta-tion procedure at the contralateral side under general anaesthesia (and after administration of oral tet-racycline). Therefore, participants will experience minimal discomfort from the biopsy procedure. Imag-ing studies and blood withdrawal will be performed on one day at one location to limit hospital visits as much as possible. Participating in this study has low risks of radiation damage (total amount approxi-mately 6 mSv, maximum amount allowed per year 10 mSv).

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

- Written informed consent
- Aged 18 years and above
- Planned to undergo a living-donor kidney transplantation, related or unrelated
- 25-hydroxyvitamin D concentrations > 50 nmol/L

Exclusion criteria

- Pregnant or lactating women, or subjects who intend to become pregnant within the study period
- Serious mental impairment i.e. preventing to understand the study protocol or comply with the study aim; potentially unreliable patients and those judged by the investigator to be unsuitable for the study
- Active, not previously treated, malignancy. Malignancies > 1 year in the medical history and treated with curative intention is not considered an exclusion criterium
- Presence of diseases known to influence bone metabolism (other than CKD MBD) such as active or chronic liver failure or cirrhosis or thyroid disease (other than benign, euthyroid nodules)
- Known allergic reaction for tetracycline antibiotics.
- Current use of calcimimetics
- Previous parathyreoidectomy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2020
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	31-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
Other	Nederlandse Trial Register

Register	ID
CCMO	NL70466.029.19