Direct validation of renal123I-MIBG scintigraphy in humans

Published: 21-03-2014
Last updated: 24-04-2024

to compare in vivo total kidney 123I-MIBG uptake (by counts per pixel) by 123I-MIBG scintigraphy to direct ex vivo 123I-MIBG uptake of the flushed kidney as directly assessed with phosphor imaging.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40382

Source
ToetsingOnline

Brief title
DIVIDERE study

Condition

- Other condition

Synonym
uptake and distribution of 123I-MIBG in the kidney (how much of the radioactive tracer 123I-MIBG is taken up by the kidney nerves)

Health condition

sympathische zenuwstelsel en intrarenale zenuwen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 123I-MIBG-scintigraphy, kidney, sympathetic nerve activity, validation

Outcome measures

Primary outcome

to compare in vivo total kidney 123I-MIBG uptake (by counts per pixel) by

123I-MIBG scintigraphy to direct ex vivo 123I-MIBG uptake of the flushed kidney

as directly assessed with phosphor imaging.

Secondary outcome

- to measure distribution of 123I-MIBG within the kidney

- to compare the quantified 123I-MIBG and distribution of 123I-MIBG as assessed

with phosphorus imaging to the histological distribution of sympathetic nerve

endings by immunohistochemical neuron staining.

- to compare 123I-MIBG uptake from in vivo renal 123I-MIBG scintigraphies, with

123I-MIBG uptake from ex vivo renal 123I-MIBG scintigraphies

- to correlate the ex vivo renal 123I-MIBG scintigraphies with the direct ex

vivo renal 123I-MIBG uptake as quantified by the phosphorus image plate.

Study description

Background summary

Metaiodobenzylguanidine (MIBG) is a noradrenalin analogue that accumulates in neurosecretory storage granules of adrenergic tissue and when labelled with 123Iodine, can be scintigraphically visualized. Since 123I-MIBG is not

metabolized, the 123I-MIBG scintigraphy storage reflects neuron integrity. This technique is clinically and experimentally used to image the sympathetic nervous system and has been validated on cardiac and adrenal tissue. Currently in two studies (i.e. ENDORSE study ABR NL36755.018.11 and RENnervate study ABR NL 42557.018.13, Dutch Trial Register numberNTR4005), 123I-MIBG scintigraphy is being used to assess sympathetic function in renal tissue. Against the expected results, the provisional results of these studies show an inter-individual highly heterogeneous renal 123I-MIBG uptake, which could be either based on a true difference or on a measurement error. It is unknown whether 123I-MIBG is mainly taken up by the adrenergic renal tissue or that the by scintigraphy visualized 123I-MIBG is mostly derived from urinary excretion. To the knowledge of the researchers, the distribution of renal 123I-MIBG content has never been studied directly and the renal 123I-MIBG scintigraphy has not been validated. To rule out a measurement error, the current study will specifically validate 123I-MIBG on kidney tissue in humans.

Study objective

to compare in vivo total kidney 123I-MIBG uptake (by counts per pixel) by 123I-MIBG scintigraphy to direct ex vivo 123I-MIBG uptake of the flushed kidney as directly assessed with phosphor imaging.

Study design

One day prior to the surgery, patients will be administered 185 mBq of 123I-MIBG intravenously and will undergo a scintigraphy on 15 minutes and 4 hours postinjection at the department of nuclear medicine. Additionally a low-dose SPECT-CT will be made 4 hours postinjection for anatomical localization.
After the kidney is surgically removed, the kidney will be taken to the nuclear medicine department and a scintigraphy will be made.
The study continues ex vivo.
The nephrectomised kidney will be taken to the nuclear medicine department and a scintigram will be made.
Directly after performing the ex vivo 123I-MIBG scintigraphy, the kidney is taken to the pathology department where the pathologist will perform the routine inspection and preparation (e.g. assessment of the tumour) and prepares 3 specimens of from healthy kidney tissue. Thereafter the kidney will be flushed with 0.9%NaCl and additionally 3 specimens will be taken.
Two of the flushed specimens and two of the unflushed specimens will be placed on the phosphousplate for 24hr.
One flushed specimen and one unflushed specimen will be brought to the neuropathology for immunohistochemical staining.

Study burden and risks

The amount of radiation the patients are exposed to is comparable to approximately 2.5 times the yearly background radiation in the Netherlands. This is an intermediate risk according to the ICRP62 (risks for 'average adults'). (see *Stralingsadvies*). The intravenous canula will be placed for the preparation of the operation anyway.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age 18 to 85 years
- able to give informed consent
- scheduled for radical nephrectomy, nephron-sparing partial nephrectomy or nephroureterectomy (only scheduled on Tuesdays to Fridays)

Exclusion criteria

- not willing to be informed about unexpected findings during the study
- pregnancy
- donor nephrectomy
- nephrectomy scheduled on Mondays

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-03-2014
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
CCMO	NL47447.018.13