Technetium 99m labelled macroaggregated albumin administered during selective arterial embolization of renal angiomyolipoma: a biodistribution study

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To assess the occurrence of lung shunting and to evaluate the biodistribution and safety of Technetium 99m labelled macroaggregated albumin (Tc-99m-MAA) after administration to the kidney.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON36687

Source
ToetsingOnline

Brief title
iRENAL

Condition

- Renal and urinary tract neoplasms benign

Synonym
angiomyolipoma, benign kidneytumour

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: Biodistribution, embolization, renal AML, Technetium MAA

Outcome measures

Primary outcome

To determine whether any shunting of Tc-99m-MAA to the lungs occurs.

Quantification of lung shunting will be performed using ROI analysis.

Secondary outcome

- To evaluate shunting of Tc-99m-MAA to the lungs by quantitative SPECT.

- To evaluate safety and toxicity.

- To evaluate the biodistribution of Tc-99m-MAA in the kidney

Study description

Background summary

A need to further improve the intra arterial treatment of renal angiomyolipoma is recognized, since current treatment options often require multiple interventions due to tumor recurrences. Intra-arterial local delivery of a therapeutic agent may lead to an overall improvement of the treatment regimen.

Study objective

To assess the occurrence of lung shunting and to evaluate the biodistribution and safety of Technetium 99m labelled macroaggregated albumin (Tc-99m-MAA) after administration to the kidney.

Study design

non-randomised, open label, uncontrolled pilot study.

Intervention

Prior to the selective arterial embolisation a dose of 150 MBq Tc-99m-MAA will be administered into the angiomyolipoma via catheter.

Study burden and risks

Patients included in this study are scheduled for a selective arterial embolization procedure. In this procedure patients will receive a 150 MBq dose of Tc-99m-MAA which corresponds to approximately 1,6mSv. Tc-99m-MAA has proven to be safe and is used frequently for diagnostic purposes. A systemic allergic reaction can occur, consisting of erythema of the skin, itching and dyspnea. Standard protocol prescribes that after the embolization procedure the patient has to rest for approximately four hours. During this time SPECT will be performed in order to determine the biodistribution. For this the patient has to lie on an examination table for one hour. Participation in this study may possibly produce useful scientific data for the future.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX UTRECHT
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX UTRECHT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients must have given written informed consent.
2. Female or male aged 18 years and over.
3. Confirmed diagnosis of AML defined by CT.
4. Clinical indication for selective arterial embolization.
5. World Health Organisation Performance status 0-2.
6. One or more lesions of at least 4 cm in the longest diameter by spiral CT.
7. Serum creatinine < 200 µmol/L.
8. Contrast enhancement of AML on CT.

Exclusion criteria

1. Patients who are mentally disabled.
2. Pregnancy or breast feeding.
3. Patients with a significant right to left cardiac shunt.
4. Patients with pulmonary hypertension.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	23-01-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Technescan Lyo-MAA
Generic name:	technetium-99m human albumin macroaggregates

Ethics review

Approved WMO Date:	01-10-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-02-2012
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
EudraCT	EUCTR2010-022275-60-NL
CCMO	NL32409.041.10