Pilot study on the influence of Sutent on tumor vascularization and necrosis in patients with renal cell carcinoma.

Published: 14-05-2007
Last updated: 14-05-2024

To observate when necrosis in metastases of renal cell cancer is occurring.

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms female benign
Study type	Observational invasive

Summary

ID

NL-OMON30373

Source
ToetsingOnline

Brief title
Sutent and tumorimaging

Condition

- Reproductive neoplasms female benign

Synonym
renal cell carcinoma renal cell cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: 4 de geldstroom: industrie vergoed de d-MRIs,Novo Nordisk

Intervention

Keyword: Dynamic enhanced magnetic resonance imaging (DCE-MRI), Renal cell carcinoma, Sutent, Tumor necrosis

Outcome measures

Primary outcome

Observational. Measurement of Kep, Ktrans, R2*, b-coefficent (perfusion,

hypoxia, blood volume and necrosis)

Secondary outcome

No

Study description

Background summary

Sutent is a new angiogenesis inhibitor. It is used in the treatment of renal cell cancer. Very frequently necrosis inside the metastases is seen after start of treatment with Sutent. After how many days this effect in the tumor is starting, is not known. We would like to investigate this, because this has consequences for future research.

Study objective

To observate when necrosis in metastases of renal cell cancer is occurring.

Study design

In 5 patients with renal cell carcinoma, which will be treated with Sutent, 3 MRIs will be made: before start, after 3 days and after 10 days.

Study burden and risks

The patient will undergo 3 times a MRI. Small risks are an allergic reaction on the contrast fluid or a hematoma due to the punction in the vein.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

P.O. Box 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

P.O. Box 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- patients with metastatic renal cell cancer for whom treatment with Sutent is planned
- measurable primary tumor or metastases (minimal diameter 2 cm) at other sites than the lungs
- Karnofsky score equal or larger than 70%
- age equal or higher than 18 year.
- written informed consent

Exclusion criteria

- contra-indications for MRI
- contra-indications for treatment with Sutentâ

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO

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	NL15264.091.06