European active surveillance of renal cell carcinoma study (E.A.S.E. RCC study)

Published: 31-08-2016
Last updated: 16-04-2024

The primary objective of this study is to assess overall survival of patients who are diagnosed with incidental, histologically (biopsy) confirmed,

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON47206

Source
ToetsingOnline

Brief title
EASE

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: CuraTrial SMO & Research
Source(s) of monetary or material Support: EAU Research Foundation of andere;nog te benaderen;sponsoren.

Intervention

Keyword: carcinoma, kidney neoplasms, registries, renal cell

Outcome measures

Primary outcome

Primary endpoint is overall survival.

Secondary outcome

Secondary endpoints are tumor growth rate, progression rate, cancer-specific survival, progression-free survival, identification of clinical and pathological variables and molecular and genetic markers that correlate with growth rate and progression.

Study description

Background summary

Active surveillance can be considered a reasonable strategy for elderly patients with small renal tumors or patients with significant comorbidities who are not good surgical candidates. However, most available studies on active surveillance include small renal tumors that were not histologically confirmed as RCCs, including a proportion of benign tumors. Furthermore, follow-up protocol and indications to delayed intervention during active surveillance have not been generally standardized. There is a clear need of information on the growth rate and oncological outcomes of histologically confirmed RCCs by percutaneous biopsy at diagnosis and on the results of a standardized protocol of active surveillance of small RCCs.
Furthermore, if the measurement of tumor growth rate seems to be helpful for initial conservative management of patients with incidentally diagnosed small renal tumors, it is necessary to identify reliable genetic or molecular serum, urine or tissue markers that can differentiate small renal tumors with different inherent aggressiveness and metastatic potential at diagnosis, thereby enabling the urologist to choose the most suitable conservative or active, individualized management approach for each patient.

Study objective

The primary objective of this study is to assess overall survival of patients who are diagnosed with incidental, histologically (biopsy) confirmed, <4 cm RCC and are managed conservatively with active surveillance.

The secondary objectives are:
o to assess growth rate and progression rate of newly diagnosed, incidental, histologically (biopsy) confirmed, <4 cm RCCs that are followed conservatively with serial imaging.
o to assess cancer-specific and progression-free survival of patients who are diagnosed with such tumors and are managed conservatively with active surveillance.
o to demonstrate that overall survival in this study population is not significantly different compared to the overall survival of the general population with similar age and co-morbidities and without RCC.
o to identify clinical and pathological prognostic factors of fast growth rate and progression for small RCCs.
o to evaluate the correlation of serum and/or urine molecular and genetic markers with growth rate and progression of small RCCs.
o to evaluate the correlation of molecular and genetic features on needle biopsies of small RCCs with growth rate and progression.

Study design

This is a prospective, multi-national clinical registry study conducted in European countries by hospital based urologists. A total of 400 patients with small, incidentally detected, histologically confirmed RCCs will be included and data related to the oncological outcomes of an active surveillance approach will be collected.

Study burden and risks

The burden and risks associated with participation in the study is considered minimal and acceptable. The number of visits is considered to be equal to standard practice. Laboratory and radiological evaluations are not considered extra and are performed according to standard practice or at the investigators discretion for monitoring possible progression of disease.
The only extra procedures are blood collection for future analyses and questionnaires completion.
By being enrolled in an active surveillance protocol, surgical treatment with the related anesthesiological and surgical risks may be avoided. Also worsening of renal function due to removal of the kidney or part of it may be avoided.
The risk of spreading of tumor cells outside the kidney while in surveillance is rare (1-2%) when delayed intervention is performed if the tumor grows or tumor-related symptoms develop.
Information learned from this study may benefit other patients who have a similar disease in the future.

Contacts

Public
CuraTrial SMO & Research

Mr. E.N. van Kleffensstraat 5
Arnhem 6842CV
NL
Scientific
CuraTrial SMO & Research

Mr. E.N. van Kleffensstraat 5
Arnhem 6842CV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

o Males or females, age >= 18 years.
o Incidental diagnosis at imaging (ultrasonography, CT, MRI) of a solid renal mass < 4 cm in maximum diameter (pT1a)
o Histologically confirmed RCC by percutaneous needle biopsy at diagnosis. All RCC subtypes are eligible for the study.
o Patients unfit for active treatment due to advanced age, or co-morbidity, or refusing active treatment.
o Signed Informed consent.
o Preparedness to comply with percutaneous tumor biopsy and a close follow-up protocol.

Exclusion criteria

o Renal tumors with a non-RCC histology (sarcomas, lymphomas, etc.).
o Tumor related symptoms at presentation.
o Patients with known genetic diseases associated with RCC (e.g. Van Hippel Landau).
o Patients unsuitable for biopsy due to need for concomitant anticoagulation or anti-platelet drug use which cannot be transiently discontinued.
o Patients unsuitable for biopsy due to tumor location or small tumor size.
o Patients with concurrent systemic treatment for another cancer.
o Patients with estimated life expectancy < 1 year.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-02-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	31-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-01-2017
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-04-2018
Application type:	Amendment
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	NL57760.091.16