Focal Ablative STereotactic RAdiosurgery for Cancers of the Kidney - A Phase II study

Published: 12-06-2019
Last updated: 12-04-2024

The primary objective of this study is to estimate the efficacy of SABR for primary RCC.

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

Summary

ID

NL-OMON48080

Source
ToetsingOnline

Brief title
FASTRACK II

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
Kidney cancer

Research involving
Human

Sponsors and support

Primary sponsor: Trans Tasman Radiation Oncology Group
Source(s) of monetary or material Support: Ministerie van OC&W,MAASTRO clinic

Intervention

Keyword: Cancer, Kidney, Radiosurgery, Stereotactic

Outcome measures

Primary outcome

Freedom from local progression, as defined by lack of progression of the target

lesion (primary RCC) as measured by RECIST criteria.

Secondary outcome

1. Toxicity, as measured by CTCAE v4.03

2. Overall survival

3. Cancer specific survival

4. Freedom from distant failure

5. Serum creatinine and estimated glomerular filtration rate (eGFR) using

CKI-EPI equation, split function and calculated glomerular filtration rate

(GFR) on nuclear medicine testing

Study description

Background summary

The standard of care for fit patients with localised kidney cancer is surgical resection of the kidney (nephrectomy). However, as renal cell carcinoma occurs mostly in the elderly population, a significant portion of patients are not able to tolerate surgery due to medical co-morbidities such as coronary heart disease. In the modern era, effective local treatment of the renal primary may become even more important as systemic targeted agents treatments improve and prolong patient survival in the first line and second line settings. However, in routine clinical practice many do not have surgery due to the associated risks and morbidity. These patients represent a group in need of an effective non-invasive alternative to surgery to control their kidney disease. Thus, an alternative local treatment to nephrectomy can potentially benefit two groups of patients: those who cannot be operated on due to medical co-morbidities; and

those patients with low volume metastatic disease where the morbidity of non-curative surgical nephrectomy limits treatment to their primary. Definitive external beam radiotherapy (EBRT) is often used to treat medically inoperable patients with cancers in many different organs. However, renal cell carcinoma (RCC) is conventionally considered *radioresistant* to fully fractionated EBRT. Stereotactic ablative body radiotherapy (SABR) is emerging as a non-invasive method for precision irradiation of tumours using doses with a higher biological effect than can be achieved with conventional radiotherapy. Stereotactic radiotherapy is typically given as three or more fractions over a period of one to two weeks.

Study objective

The primary objective of this study is to estimate the efficacy of SABR for primary RCC.

Study design

FASTRACK II is a single arm, multi-institutional phase II study. All participants will receive SABR as definitive treatment for their primary renal cell carcinoma.

Intervention

- Radiation (in a schedule of 26 Gy in 1 fraction or 42Gy in 3 fractions);
- Questionnaires;
- CT's thorax/abdomen;
- Bloodwithdrawals;
- Split renal function study;
- Consultations.

Study burden and risks

SABR is very precise radiatoin, which will cause some burden. Most of the investigations to monitor the patient will be done in standard practice. The rest of the investigations are done to monitor the patient closely and measure the effect of the treatment. Even though a certain burden and risk are part of the trial, the treatment can have a positive effect on a better controle of the tumor and thus on survival of the patient.

Contacts

Public
Trans Tasman Radiation Oncology Group

Waratah PO 88
Waratah 88
AU
Scientific
Trans Tasman Radiation Oncology Group

Waratah PO 88
Waratah 88
AU

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age > 18 years old
- All patients must have a biopsy confirmed diagnosis of RCC with no more than a single lesion within a kidney (bilateral RCC is allowable)
- ECOG performance of 0-2 inclusive
- Life expectancy > 9 months
- Either medically inoperable, technically high risk for surgery or decline surgery
- Provide written informed consent
- A multidisciplinary decision has been made that active treatment is warranted

Exclusion criteria

- Pre-treatment estimated glomerular filtration rate < 30 mls/min
- Prior systemic therapies for RCC
- Previous high-dose radiotherapy to an overlapping region (defined as BED>40Gy using an a/B* ratio of 10, please see FASTRACK II Radiotherapy Planning, Delivery and QA guidelines section 8.4.1)

- Tumours larger than 10cm in size
- Direct contact of the target tumour with bowel
- Untreated prior malignancy, or prior malignancy within 2 years of screening
- Visceral / Bony metastatic disease
- Horseshoe kidney

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-11-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT02613819
CCMO	NL67405.068.18