ISRCTN19562321 https://doi.org/10.1186/ISRCTN19562321

Clinical trial to assess the importance of nephrectomy

Submission date	Recruitment status	[_] Prospectively registered
21/09/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/11/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2022	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-combination-surgery-sunitinib-kidney-cancer-carmena

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00930033

Secondary identifying numbers
P_070144

Study information

Scientific Title
Randomized phase III trial evaluating the importance of nephrectomy in patients presenting with metastatic renal cell carcinoma treated with sunitinib

Acronym
CARMENA

Study objectives
We are investigating whether removal of the kidney tumour (known as nephrectomy) is of benefit in patients whose tumour has already spread to other organs (known as metastasis). In the past the standard treatment for many patients with kidney cancer that had spread to other organs was a drug called Interferon. In some patients who were treated with Interferon removing the kidney containing the tumour was shown to improve the length of time patients survived. New drugs (like Sunitnib) are now available for the treatment of kidney cancer which have been shown to be much more effective than Interferon and we do not know if removing the kidney is still of benefit to patients. If nephrectomy is no longer needed this would avoid a major operation. The purpose of this study is to see if nephrectomy is of benefit in patients receiving Sunitinib who have a tumour in their kidney with metastasis at the time of diagnosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 1, Glasgow, 20/12/2010 (re-issued 18/01/2011), ref: 10/S0703/66

Study design
International multi-centre non-inferiority randomised phase III trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Metastatic renal cell carcinoma, clear cell carcinoma (the most common type of renal cell carcinoma).

Interventions
Treatment Arms:
Arm A: Nephrectomy followed by Sunitinib
Arm B: Sunitinib alone

Sunitinib will be administered orally daily for 4 weeks followed by a 2 week rest (4/2 schedule). A cycle is considered 6 weeks. Sunitinib starting dose is 50 mg daily with provision for dose reduction based on tolerability. Patients will be treated until disease progression, occurrence of unacceptable toxicity or withdrawal.

For patients randomised to Arm A (nephrectomy plus Sunitinib):
1. The time between randomisation and nephrectomy should not exceed 28 days.
2. Treatment with Sunitinib will be started, as far as possible, between the 3rd week and the end of the 6th week following nephrectomy.

For patients randomised to Arm B (Sunitinib alone):
1. Sunitinib will be started within the 21 days following randomisation.
2. Sunitinib will be administered in 28 day cycles separated by 2 weeks off (4/2 schedule)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Sunitinib

Primary outcome measure
To evaluate the importance of initial nephrectomy for the subsequent survival of patients with metastatic renal cell carcinoma treated with sunitinib. This is calculated by the time between the date of randomisation and the date of death, irrespective of cause of death.

Secondary outcome measures
1. Tumour response
2. Progression free survival- Progression-free survival is calculated by the time between the date of randomisation and the date of progression or the date of initiating second-line treatment. Patients who have died from other causes are recorded on the date of death. Patients who are alive and progression-free when last heard of are recorded on the date of the last visit.
3. The percentage of patients who cannot start Sunitinib treatment within 6 weeks postoperatively on Arm A (nephrectomy + Sunitinib)
4. The need to perform nephrectomy in Arm B (Sunitinib alone)
5. Postoperative morbidity is evaluated using the Clavien scales
6. Postoperative mortality is evaluated by the percentage of deaths within the 30 days following nephrectomy.
7. Tolerability, particularly changes in renal function over time is evaluated by the NCI-CTC v3 scales

Overall study start date
01/08/2009

Completion date
26/05/2015

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Eastern Cooperative Oncology Group (ECOG) Performance Status 0 - 1
3. Biopsy (primary tumour or metastases) confirming the diagnosis of clear cell carcinoma alone or preponderant
4. Documented metastatic disease
5. Absence of prior systemic treatment for kidney cancer including anti angiogenic (AA)
6. Tumour amenable to nephrectomy (partial or total) in the opinion of the patients urologist. Patients presenting with an inferior vena cava thrombosis can be included.
7. Patients for which the indication of Sunitinib is considered according to the recommendations rules given by national health authorities of participating countries. The prescription of Sunitinib in the circumstances of the study is considered as a standard treatment
8. Platelets 100 x 109/L, haemoglobin > 9 g/dl, neutrophils >1.5 x 109/L
9. Bilirubin < 2 mg/dL, aspartate transaminase (ASAT) and alanine transaminase (ALAT), 2.5 times the upper normal limit (UNL) or 5 times UNL for patients with liver metastases
10. Patients of child bearing age should use contraceptive methods
11. Patient able to follow the procedures outlined in the protocol as far as the planning of visits and examinations are concerned
12. Life expectancy ≥ 3 months
13. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1134

Total final enrolment
450

Key exclusion criteria
1. Prior systemic treatment for kidney cancer (including anti angiogenic)
2. Bilateral kidney cancer
3. Pregnant or breast feeding women
4. Acute coronary syndrome or episode of myocardial infarction or severe or unstable angina within the last 6 months as well as severe diabetes with severe peripheral arteriopathy or deep

phlebitis or arterial thrombosis within the last 3 months
5. Anticoagulant therapy in treatment dose
6. Medical, general or psychiatric difficulties which, in the opinion of the Investigator, would make it inappropriate for trial entry
7. Brain metastases
8. Previous history of gastric disease or of malabsorption compromising the absorption of Sunitinib
9. Experimental treatment within the 28 days preceding inclusion
10. Other cancer within the previous 5 years [except for insitu skin carcinoma and treated localised prostate cancer with undetectable Prostate-specific antigen (PSA)]

Date of first enrolment
26/05/2011

Date of final enrolment
25/08/2014

Locations

Countries of recruitment
France

Greece

Norway

Poland

United Kingdom

Study participating centre
Hopital Europeen Georges Pompidou (HEGP)
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Sponsor information

Organisation
NHS Greater Glagsow and Clyde (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/content/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK's CTAAC Committee (UK)

Funder Name
National Cancer Research Network (NCRN) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
02/08/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/08/2018	10/04/2019	Yes	No

Plain English results	14/10/2020	No	Yes