

# SORCE: a phase III randomised double-blind study comparing SOrafenib with placebo in patients with Resected primary renal CELL carcinoma at high or intermediate risk of relapse

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| <b>Submission date</b><br>31/05/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/08/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>08/04/2021       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-sorafenib-or-placebo-after-surgery-for-kidney-cancer-that-has-not-spread>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

ClinicalTrials.gov (NCT)

NCT00492258

## Clinical Trials Information System (CTIS)

2006-006079-19

### Protocol serial number

ACTRN12609000048280; RE05

## Study information

### Scientific Title

SORCE: a phase III randomised double-blind study comparing SOrafenib with placebo in patients with Resected primary renal CELL carcinoma at high or intermediate risk of relapse

### Acronym

SORCE

### Study objectives

SORCE aims to answer two questions:

1. Whether at least one year of treatment with sorafenib increases Disease-Free Survival (DFS) compared with placebo.
2. Whether three years of treatment with sorafenib increases DFS compared to one year of treatment.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

South East Research Ethics Committee, South East Coast Health Authority, 02/04/2007, ref: 07 /MRE01/10

### Study design

Randomised double-blind placebo-controlled multi-centre study

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Primary renal cell carcinoma

### Interventions

Patients will be randomly assigned to one of the following:

Arm A: 3 years of placebo

Arm B: 1 year of sorafenib followed by 2 years of placebo

Arm C: 3 years of sorafenib

Sorafenib will be given at 400 mg po (per oral) bd (twice daily) doses. Patients with disease progression who are in Arm A or B within 3 years of start of treatment whilst on placebo will be offered compassionate use of sorafenib at the standard dose of 400 mg po bd until further progression/toxicity. This is referred to throughout the protocol as open-label sorafenib.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Sorafenib

## **Primary outcome(s)**

Disease Free Survival (DFS) (i.e. time from randomisation to first evidence of local recurrence or distant metastases or death from RCC)

## **Key secondary outcome(s)**

1. RCC-specific survival time (i.e. time to death from RCC)
2. Overall Survival (OS)
3. Cost effectiveness
4. Toxicity
5. Biological characteristics of resected primary RCC:
  - 5.1. von Hippel Lindau (VHL) protein
  - 5.2. Vascular Endothelial Growth Factor Receptor-2 (VEGFR2)
  - 5.3. Fibroblast Growth Factor 2 (FGF2)
  - 5.4. B-Raf
  - 5.5. MAPK ERK kinase (MEK)
  - 5.6. Extracellular signal-Regulated Kinase (ERK)
6. Corroboration of Leibovich Prognostic Score (9 years after first patient entry)

## **Completion date**

01/06/2012

## **Eligibility**

### **Key inclusion criteria**

1. Histologically proven Renal Cell Carcinoma (RCC)
2. No evidence of residual macroscopic disease on post-operative Computed Tomography (CT) scan after resection of RCC. Patients with clear cell or non-clear cell tumours are eligible
3. Patients with 'Intermediate' or 'High' risk per the Leibovich score 3 to 11
4. Subjects must be >18 years of age
5. Women of childbearing age must have a negative pregnancy test and must use adequate contraception during the treatment phase of the study and for 9 months afterwards. Women who wish to breastfeed are not eligible for the study
6. Adequate bone marrow function (White Blood Cells > 3.4x10<sup>9</sup>/l, platelets > 99x10<sup>9</sup>/l), renal function (creatinine < 2.5 x upper limit of normal and hepatic function (liver function test [LFT] < 1.5 x upper limit of normal) within 14 days prior to randomisation
7. Patients should have had surgery at least 4 weeks but no more than 3 months prior to

treatment start date

8. Serum amylase < 1.5 x upper limit of normal

9. ProThrombin (PT) or International Normalized Ratio (INR) and ProThrombin Time (PTT) < 1.5 x upper limit of normal

10. World Health Organization Performance Status 0 or 1

11. Written Informed Consent obtained

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

1711

### **Key exclusion criteria**

1. Prior anti-cancer treatment for RCC other than nephrectomy

2. Cardiac arrhythmias requiring anti-arrhythmics (beta-blockers and digoxin are allowed), symptomatic coronary artery disease or ischaemia, myocardial infarction within the last 6 months, congestive cardiac failure > NYHA Class II

3. Active clinically serious bacterial or fungal infections

4. Known history of human immunodeficiency virus (HIV) infection or chronic hepatitis B or C

5. Pregnant or breastfeeding patients. Women of childbearing potential must have a negative pregnancy test performed within seven days prior to the start of study drug. Both men and women enrolled in this trial must use adequate birth control

6. Prior malignancy (except for cervical carcinoma in situ or adequately treated basal cell carcinoma)

7. Concomitant medications which have adverse interactions with sorafenib: rifampin, grapefruit juice, ritonavir, ketoconazole, itraconazole and St John's Wort

8. Patients with uncontrolled hypertension

### **Date of first enrolment**

01/06/2007

### **Date of final enrolment**

01/06/2012

## **Locations**

### **Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Addenbrooke's Hospital**

Cambridge

United Kingdom

CB2 2RE

## Sponsor information

**Organisation**

Medical Research Council (UK)

**ROR**

<https://ror.org/03x94j517>

## Funder(s)

**Funder type**

Government

**Funder Name**

Medical Research Council (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Cancer Research UK, Clinical Trials Advisory and Awards Committee (CTAAC)

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

### Funder Name

Bayer (educational grant plus free Sorafenib/matched placebo for all patients) (International)

### Alternative Name(s)

Bayer AG, Bayer Corporation, Friedr. Bayer et. comp.

### Funding Body Type

Government organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

Germany

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

| Output type                           | Details              | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------------|----------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>       | results              | 11/12/2012   |            | Yes            | No              |
| <a href="#">Results article</a>       | results              | 01/02/2018   |            | Yes            | No              |
| <a href="#">Results article</a>       |                      | 01/12/2020   | 08/04/2021 | Yes            | No              |
| <a href="#">Abstract results</a>      | baseline information | 01/02/2014   |            | No             | No              |
| <a href="#">Plain English results</a> |                      |              |            | No             | Yes             |