# 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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
31/05/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/08/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
N8/N4/2N21	Cancer			

#### 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

**Prof Tim Eisen** 

#### **Contact details**

Oncology Centre Box 193 Addenbrooke's Hospital Robinsons Way Cambridge United Kingdom CB2 2RE

tgqe2@cam.ac.uk

# Additional identifiers

Clinical Trials Information System (CTIS)

2006-006079-19

#### ClinicalTrials.gov (NCT)

NCT00492258

#### 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 > 3.4x109/l, platelets > 99x109/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  $< 1.5 \times 1.5$
- 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, 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?
Results article	results	11/12/2012		Yes	No
Results article	results	01/02/2018		Yes	No
Results article		01/12/2020	08/04/2021	Yes	No
Abstract results	baseline information	01/02/2014		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes