

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

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 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?
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
Plain English results				No	Yes