ISRCTN38934710 https://doi.org/10.1186/ISRCTN38934710

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

Registration date
30/08/2007

Overall study status
Completed

Last Edited
08/04/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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

EudraCT/CTIS number
2006-006079-19

IRAS number

ClinicalTrials.gov number
NCT00492258

Secondary identifying numbers
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

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 to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
01/06/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1656

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
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2RE

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
MRC Centre London
Second Floor
Stephenson House
158-160 North Gower Street
London
United Kingdom
NW1 2ND
-
iv@centre-london.mrc.ac.uk

Sponsor type
Government

Website
http://www.ctu.mrc.ac.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, 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

Publication and dissemination plan
Lawrence NJ, Martin A, Davis ID, Troon S, Sengupta S, Hovey EJ, et al. Predicted benefits of adjuvant sorafenib after nephrectomy for renal cell carcinoma (RCC) in SORCE: an international, placebo-controlled, randomised phase 3 trial. ESMO-2017 2017; abstr. 881P. Available from: URL: http://www.esmo.org/Conferences/ESMO-2017-Congress

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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