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Adjuvant interleukin-2, interferon-alpha and 5-fluorouracil for patients with high risk of relapse after surgical treatment for renal cell carcinoma

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 28/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-000857-50

IRAS number

ClinicalTrials.gov number
NCT00053807

Secondary identifying numbers
EORTC 30955

Study information

Scientific Title
Adjuvant interleukin-2, interferon-alpha and 5-fluorouracil for patients with high risk of relapse after surgical treatment for renal cell carcinoma

Study objectives
1. Compare the effect of adjuvant combination therapy comprising interleukin-2, interferon alfa, and fluorouracil versus observation only on disease-free survival or overall survival of patients with renal cell carcinoma at high risk of relapse after radical surgery.
2. Compare the quality of life of patients treated with these regimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics approval information required at time of registration

Study design
Randomised controlled 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cancer, kidney

Interventions
This is a randomised, multicenter study. Patients are randomised to one of two treatment arms:
Arm 1: Patients receive interleukin-2 subcutaneously (SC) on days three, four, and five of weeks one and four and on days one, three, and five of weeks two and three. Patients also receive interferon alfa SC once weekly during weeks one and four and three times weekly during weeks

two, three, five, six, seven, and eight. Patients then receive fluorouracil IV on day one of weeks five, six, seven, and eight.
Arm 2 (control arm): Patients receive no adjuvant treatment before disease progression.

Quality of life is assessed at baseline and at two and six months after randomisation.
Patients are followed monthly for three months (arm one only), every three months for one year, every six months for four years, and then annually thereafter.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Interleukin-2, interferon-alpha, 5-fluorouracil

Primary outcome measure
Disease-free survival or overall survival

Secondary outcome measures
Quality of life

Overall study start date
19/02/1999

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Surgical resection of primary renal cell carcinoma. A lymph node dissection to differentiate between N+ and N- is optional. Removal of clinical N+ disease is obligatory
2. No metastatic or macroscopic residual disease
3. Patients should have:
1.1. Histologically proven T3b, T3c or T4 tumour or Any pT stage and nodal status pN1/2 or
1.2. Any pT stage and microscopic positive margins or
1.3. Presence of any microscopic vascular invasion
4. World Health Organisation (WHO) performance status zero or one
5. Aged 75 years or less
6. White Blood Cells (WBC) more than or equal to 3.5 x 10^9/l, platelets more than or equal to 100 x 10^9/l
7. Liver Function Tests (LFTs) less than or equal to 1.25 x Upper Limit of Normal (ULN), serum creatinine less than 1.5 x ULN
8. Randomisation to be carried out as close as possible to the time at which adjuvant surgery would begin, but no later than 12 weeks following surgery
9. Informed consent of the patient

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
214

Key exclusion criteria
1. Unstable angina or Myocardial Infarction (MI)
2. Active infection requiring antibiotic
3. Major organ allograft
4. Patients likely to require corticosteroids for intercurrent disease
5. Pregnant/lactating women
6. Patients with concomitant or previous malignancies
7. Patients who have received radiation or chemotherapy

Date of first enrolment
19/02/1999

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Cancer Research UK Clinical Trials Unit (Beatson)
Glasgow
United Kingdom
G11 6NT

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details

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Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK)

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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	20/05/2011	28/01/2019	Yes	No