

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
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 28/01/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00053807

Clinical Trials Information System (CTIS)

2004-000857-50

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Disease-free survival or overall survival

Key secondary outcome(s)

Quality of life

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 $3.5 \times 10^9/l$, platelets more than or equal to $100 \times 10^9/l$
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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

Cancer Research UK Clinical Trials Unit (Beatson)

Glasgow

United Kingdom

G11 6NT

Sponsor information

Organisation

Cancer Research UK (CRUK) (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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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	20/05/2011	28/01/2019	Yes	No
Plain English results				No	Yes