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A randomised controlled trial of Interferon-alpha (IFN-alpha), Interleukin-2 (IL-2) and 5 Fluorourcil (5-FU) versus Interferon-alpha alone in patients with advanced renal cell carcinoma

Submission date 08/11/2000	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/11/2000	**Overall study status** Completed	
Last Edited 18/10/2018	**Condition category** Cancer	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=61

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00053820

Protocol serial number
RE04 (E164/5)

Study information

Scientific Title
A randomised controlled trial of Interferon-alpha (IFN-alpha), Interleukin-2 (IL-2) and 5 Fluorourcil (5-FU) versus Interferon-alpha alone in patients with advanced renal cell carcinoma

Study objectives
1. The value of triple combination therapy in terms of overall survival in patients with advanced metastatic renal cell carcinoma compared with IFN-alpha alone
2. The value of triple combination therapy in terms of progression-free survival time and toxicity compared with IFN-alpha alone
3. The Quality of Life of patients in both treatment arms during therapy and follow-up
4. The health economic implications of using triple therapy compared to the control regimen

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Renal Cancer

Interventions
Arm 1: IFN-alpha until progression
Arm 2: IFN-alpha, IL-2 and 5-FU (max 2 cycles)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Interferon-alpha (IFN-alpha), Interleukin-2 (IL-2) and 5 Fluorourcil (5-FU)

Primary outcome(s)
The primary endpoint is survival. The primary endpoint, which will be used to evaluate the efficacy of the treatment regimens, will be time to death. All deaths should be reported immediately and time to death will be calculated from the date of randomisation.

Key secondary outcome(s))

1. Time to disease progression. Progression is defined according to the RECIST guidelines
2. Comparison of toxicity levels, principally grade III/IV
3. Quality of life will be assessed before, during and after treatment
4. The impact of the treatment regimens on health economics will also be evaluated

Completion date
31/07/2006

Eligibility

Key inclusion criteria
1. Histologically proven renal cell carcinoma. Material may be obtained from the primary tumour or the metastases
2. Advanced metastatic disease that, in the opinion of the investigator, requires treatment. (We would recommend that patients have undergone resection of their primary tumour prior to entry into the trial but this is not mandatory)
3. At least one measurable lesion. Measurements must be taken within the 4 week period before the start of treatment (single bone lesions should not be included due to assessing response)
4. WHO performance status 0 or 1
5. Normal haematological parameters (WBC >3 x 109/l; platelets >100 x 109/l; haemoglobin >10g /dl). This assessment should be carried out within 7 days before randomisation
6. Creatinine levels must be within normal limits for institution. If creatinine raised, then EDTA or creatinine clearance should be greater than 60ml/min
7. Life expectancy greater than 12 weeks
8. Written informed consent
9. Male or female patient of any ethnic group more than 18 years in age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. No radiotherapy to target lesions during trial therapy
2. Previous chemotherapy, endocrine therapy or treatment with biological agents
3. No current or previous brain metastasis
4. Unstable angina pectoris or recent (6 month) myocardial infarction
5. Evidence of active infections requiring antibiotic therapy
6. Patients with major organ allografts (IL-2 may increase T-cell mediated rejection and immunosuppressive agents are likely to reduce efficacy of IL-2 and IFN-alpha

7. Patients who require or are likely to require corticosteroids for intercurrent disease
8. Pregnant or lactating women
9. Other disease or previous malignancy likely to interfere with the protocol treatments or comparisons
10. Patients with concurrent malignancy, unless they have remained free of the disease attributed to the malignancy for more than 5 years

Date of first enrolment
24/04/2001

Date of final enrolment
31/07/2006

Locations

Countries of recruitment
United Kingdom

England

Belgium

Denmark

Germany

Netherlands

Slovakia

Study participating centre
Royal Marsden Hospital
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name
Medical Research Council (MRC) (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

Results and Publications

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?
Results article	results	20/02/2010		Yes	No
Other publications	rationale and progress	01/08/2005		Yes	No
Plain English results				No	Yes