

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/11/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=61

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00053820

Secondary identifying numbers

RE04 (E164/5)

Study information

Scientific Title

A randomised controlled trial of Interferon-alpha (IFN-alpha), Interleukin-2 (IL-2) and 5 Fluorouracil (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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

24/04/2001

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 $>3 \times 10^9/l$; platelets $>100 \times 10^9/l$; 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1100

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**

Belgium

Denmark

England

Germany

Netherlands

Slovakia

United Kingdom

Study participating centre

Royal Marsden Hospital

London

United Kingdom

SW3 6JJ

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent

London

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+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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

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