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A randomised trial of alpha-interferon versus medroxyprogesterone acetate for metastatic renal carcinoma

Submission date 28/02/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 04/09/2009	**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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REO1

Study information

Scientific Title

Study objectives
To establish whether, in patients with metastatic renal carcinoma, recombinant alpha-interferon has any advantage over medroxyprogesterone acetate.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
1. One group receives recombinant alpha-interferon
2. The other group receives medroxyprogesterone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
alpha-interferon versus medroxyprogesterone acetate

Primary outcome measure

1. Survival time
2. Response rate
3. Time to progression
4. Quality of life

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1992

Completion date
01/12/1998

Eligibility

Key inclusion criteria
1. Histologically or cytologically proven renal cell carcinoma with evaluable metastatic disease
2. World Health Organisation (WHO) performance status 0-2
3. No previous malignancy (except non-melanotic skin cancer or in situ carcinoma of the cervix)
4. Three groups of patients are eligible:
(a) Those patients who have had a nephrectomy in the past and develop metastatic disease during follow up. Patients can be randomised when metastatic disease has been confirmed and the patient fits the other eligibility criteria.
(b) Those patients who present with metastatic disease and have had the primary tumour removed within the last 4 weeks. Patients should be randomised once the nephrectomy has been performed and the wound has healed.
(c) Those patients who present with metastatic disease where nephrectomy is not planned. Patients can be randomised at presentation.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
600

Key exclusion criteria
Patients with cardiac disease which may preclude alpha-interferon or those with known brain metastases must be excluded. No previous RT, hormonal, cytotoxic or immuno-therapy within 12 weeks of the proposed date of randomisation.

Date of first enrolment
01/01/1992

Date of final enrolment
01/12/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

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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?
Other publications	design described	15/11/1994		Yes	No
Results article	early results	02/01/1999		Yes	No
Results article	results	23/02/2004		Yes	No