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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/02/2001		Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/02/2001	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/09/2009	Cancer			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mrs Pat Cook

#### Contact details

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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)

# Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +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?
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