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# Interferon alpha in combination with thalidomide in the treatment of metastatic renal cell carcinoma - a randomised phase II study

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| **Submission date**<br>19/08/2002 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Stopped | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>25/01/2019 | **Condition category**<br>Cancer | [ ] Individual participant data<br>[ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00027664

**Protocol serial number**
CO0.024

# Study information

### Scientific Title
Interferon alpha in combination with thalidomide in the treatment of metastatic renal cell carcinoma - a randomised phase II study

### Study objectives
Not provided at time of registration

### 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
Metastatic renal cell carcinoma

### Interventions
Two arms:
1. Interferon-alpha three times per week. The first three doses will be 4.5 miu, 4.5 miu, 9 mui, then 9 mui six times each fortnight, for 12 weeks initially, then for a further 12 weeks if stable disease or better. Then 12-weekly cycles until progression.
2. Interferon-alpha and thalidomide. Interferon as above. Thalidomide 200 mg per day orally to be taken at night at least 2 h after the evening meal.

### Intervention Type
Drug

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
Interferon alpha, thalidomide

### Primary outcome(s)
Not provided at time of registration

### Key secondary outcome(s))
Not provided at time of registration

### Completion date
01/01/2004

## Eligibility

### Key inclusion criteria
1. Measurable progressive disease (greater than 1 cm non-irradiated marker lesions)
2. Calculated creatinine clearance greater than 60 ml/min or ethylene diamine tetra-acetic acid (EDTA) clearance greater than 40 ml/min
3. Normal bilirubin
4. Liver enzymes less than 5 x upper limit of normal range

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/02/2001

### Date of final enrolment
01/01/2004

## Locations

### Countries of recruitment
United Kingdom

England

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

# Sponsor information

**Organisation**
UK Co-ordinating Committee for Cancer Research (UKCCCR)

**ROR**
https://ror.org/054225q67

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Not provided at time of registration

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration