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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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

Primary study design
Interventional

Study design
Randomised controlled trial

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