

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	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 25/01/2019	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

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