

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 <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/01/2019	Condition category Cancer	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00027664

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2001

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details

MRC Clinical Trials Unit

222 Euston Road

London

United Kingdom

NW1 2DA

Sponsor type

Government

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

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