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A phase II randomised study of cisplatinum and nifedipine in end stage carcinoma of the head and neck

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/03/2015	**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
- - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LIVERPL-HN1

Study information

Scientific Title
A phase II randomised study of cisplatinum and nifedipine in end stage carcinoma of the head and neck

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
Head and neck cancer

Interventions
Patients are randomised to one of two treatment regimens:
1. Group A: Cisplatinum repeated every 21 days for a maximum of six cycles
2. Group B: Cisplatinum plus nifedipine repeated every 21 days for a maximum of six cycles

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Cisplatinum and nifedipine

Primary outcome measure

Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
01/01/2004

Eligibility

Key inclusion criteria
1. Patients with either advanced squamous cell carcinoma of the head and neck, not previously treated, or recurrent squamous cell carcinoma of the head and neck after previous radiotherapy or surgery
2. Measurable histologically confirmed, squamous cell carcinoma of the head and neck. The primary sites will be:
2.1. Mouth
2.2. Nasopharynx
2.3. Oropharynx
2.4. Hypopharynx
2.5. Larynx
2.6. Nose and sinuses
2.7. Middle ear
3. No prior chemotherapy
4. Not suitable for surgery or radiotherapy with a curative purpose
5. Karnofsky performance greater than 50
6. Minimum of three weeks since prior radiotherapy and or surgery and patients must have fully recovered from such prior treatments
7. Adequate bone marrow and renal function
8. No active infection
9. No concomitant or prior malignancy except adequately treated basal cell carcinoma of the skin and in situ carcinoma of the uterine cervix

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2003

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
North West Cancer Research Fund (UK)

Sponsor details
22 Oxford Street
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Sponsor type
Research organisation

ROR
https://ror.org/025qv0671

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