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

Submission date	Recruitment status	[X] Prospectively registered
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	Results
Last Edited	Condition category	[] Individual participant data
10/03/2015	Cancer	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

Type(s)

Scientific

Contact name

- - -

#### Contact details

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

# 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 Liverpool United Kingdom L7 7BL +44 (0)151709 2919 GenSec@cancerresearchnorthwest.co.uk

## 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