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A randomised phase II trial of the antiemetic effects of Nozinan® compared to a standard dexamethasone containing protocol

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 25/05/2016	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0084096585

Study information

Scientific Title
A randomised phase II trial of the antiemetic effects of Nozinan® compared to a standard dexamethasone containing protocol

Study objectives
How does the antiemetic effects of dexamethasone and levomepromazine (Nozinan®) compare in the treatment of delayed emesis in patients receiving a cisplatin-based chemotherapy regimen (ECF)?

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
Vomiting, delayed chemotherapy-induced emesis (DCIE)

Interventions
Randomised controlled trial comparing (a) study treatment (ie Nozinan®) and (b) standard treatment (ie dexamethasone and Maxolon®).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Dexamethasone, levomepromazine (Nozinan®), metoclopramide (Maxalon®)

Primary outcome measure
Reduction in emesis.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2000

Completion date
31/03/2006

Eligibility

Key inclusion criteria
196 Patients, 93 in each arm.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
186

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/09/2000

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Oncology
Hull
United Kingdom
HU8 9HE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Industry

Funder Name
Link Pharmaceuticals (UK)

Funder Name
NHS R&D Support Funding (UK)

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