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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Reduction in emesis.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/03/2006

Eligibility

Key inclusion criteria
196 Patients, 93 in each arm.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Department of Oncology
Hull
United Kingdom
HU8 9HE

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Industry

Funder Name
Link Pharmaceuticals (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration