

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
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 25/05/2016	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

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

Primary study design

Interventional

Study design

Randomised controlled trial

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