

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/05/2016	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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