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Dexamethasone Reduces Emesis After Major gastrointestinal Surgery (DREAMS trial)

Submission date 26/06/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/06/2012	**Overall study status** Completed	
Last Edited 20/04/2017	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.DREAMS.bham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-022894-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10426

Study information

Scientific Title
Dexamethasone Reduces Emesis After Major gastrointestinal Surgery (DREAMS trial) - a prospective, double-blind, multicentre, randomised control trial

Acronym
DREAMS

Study objectives
Postoperative nausea and vomiting (PONV) is one of the most common complications affecting patients after major surgery. Patients undergoing bowel surgery are at a relatively high risk of developing these symptoms. This is often multifactorial and such patients are often exposed to various causative agents. Following surgery, patients view nausea and vomiting as a very undesirable effect, often reported as even more unpleasant than pain. It can cause significant consequences and given that over 60,000 bowel operations are performed in the UK annually, PONV is important because of its implications. Although the final outcome of surgery is rarely affected, PONV can cause significant complications such as dehydration, delayed return to oral diet, physiological disturbances and thus prolonging hospital stay. Delayed recovery predisposes to serious and life threatening complications such as hospital acquired pneumonia and thromboembolic events (deep vein thrombosis and pulmonary embolism). The delay in resuming an oral diet affects nutrition and subsequent general well being, predisposing to tissue breakdown, wound infection, fatigue, and weakness. For these reasons, reducing the severity of PONV is particularly important.

Dexamethasone is a steroid drug widely but not universally used in attempt to prevent PONV by anaesthetists, and single dose dexamethasone has been reported to reduce PONV and perioperative fatigue. Its precise mechanism of action is unknown but it has antiemetic properties and is known to improve appetite aiding early recovery.

Small studies have shown a reduction in PONV amongst patients undergoing various types of surgery who are given dexamethasone. However no multicentre trial has been undertaken. Its potential benefits for patients undergoing bowel surgery need to be investigated. The findings would ensure its appropriate use in the future.

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H0402/77; First MREC approval date 16/02/2011

Study design
Randomised; Interventional; Design type: Prevention

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network, Oral and Gastrointestinal, Generic Health Relevance and Cross Cutting Themes; Subtopic: Colorectal Cancer, Oral and Gastrointestinal (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Colon, Gastrointestinal, Surgery

Interventions
Patients are randomized between 8 mg intravenous dexamethasone and control (no dexamethasone)

Follow Up Length: 1 month(s)

Intervention Type
Procedure/Surgery

Phase
Phase IV

Primary outcome measure
Number of episodes of vomiting recorded prospectively 24 hours post-op

Secondary outcome measures
1. Fatigue measured one month post-op
2. Frequency of use of post-op anti-emetics measured one month post-op
3. Length of hospital stay
4. Subjective measure of PONV measured one month post-op
5. Time to tolerating oral diet measured one month post-op

Overall study start date
20/06/2011

Completion date
23/07/2015

Eligibility

Key inclusion criteria
1. All patients undergoing laparoscopic and open colorectal resections for malignant or benign pathology
2. Male & Female; Upper Age Limit 90 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 950; total number of patients recruited: 1350

Key exclusion criteria
1. Obstructed procedures
2. Pregnant patients
3. Known adverse reaction to dexamethasone
4. Patients currently taking any form of steroid medication
5. Diabetic/hyperglycaemic patients
6. Active gastric ulceration
7. Wideangle glaucoma
8. Patients under the age of 18
9. Patients unable or unwilling to give informed consent

Date of first enrolment
20/06/2011

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TH

Study participating centre
49 sites in the UK
United Kingdom
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Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

Website
http://www.bham.ac.uk

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Bowel Disease Research Foundation

Alternative Name(s)
BDRF

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Research for Patient Benefit (RfPB) (UK)

Results and Publications

Publication and dissemination plan
1. Collaborators across the UK will have the results presented to them
2. Patients will be sent a summary of the results in letter form
3. The main publication of results will be submitted to a major journal
4. The results will be sent to NICE
5. The publication of the results will be available on the University of Birmingham website

Intention to publish date
01/08/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/08/2013		Yes	No
Results article	results	18/04/2017		Yes	No
HRA research summary			28/06/2023	No	No