

Dexamethasone Reduces Emesis After Major gastrointestinal Surgery (DREAMS trial)

Submission date 26/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/04/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Study website

<http://www.DREAMS.bham.ac.uk>

Contact information

Type(s)

Scientific

Contact name

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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 hypothesis

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

Condition

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

Overall study end date

23/07/2015

Eligibility

Participant 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

Participant 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

Recruitment start date

20/06/2011

Recruitment end date

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