ISRCTN15943548 https://doi.org/10.1186/ISRCTN15943548

Attenuation of haemodynamic response to tracheal intubation with oral gabapentin and midazolam in breast cancer patients

Submission date 09/03/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/03/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/03/2017	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
A modified radical mastectomy is a procedure in which the entire breast is removed in order to remove breast cancer. A flexible plastic tube is placed into the trachea (windpipe) to keep the airway open (tracheal intubation). The aim of this study is to find out whether the drugs midazolam and gabapentin can reduce the stress response (increased heart rate and blood pressure) to tracheal intubation.

Who can participate?
Patients aged between 18 and 65 undergoing modified radical mastectomy

What does the study involve?
Participants are randomly allocated into two groups. One group is given oral gabapentin and midazolam 90 minutes before intubation. The other group is given gabapentin 90 minutes before intubation. Heart rate, blood pressure, sedation and side effects are measured to see whether gabapentin and midazolam can reduce the stress response to tracheal intubation.

What are the possible benefits and risks of participating?
The results of this study will increase scientific knowledge and may benefit future patients.

Where is the study run from?
National Cancer Institute, Cairo University (Egypt)

When is the study starting and how long is it expected to run for?
February to June 2017

Who is funding the study?
National Cancer Institute, Cairo University (Egypt)

Who is the main contact?
Dr Ahmed Bakir
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201617009.2p

Study information

Scientific Title
Attenuation of haemodynamic response to tracheal intubation with oral gabapentin and midazolam in breast cancer patients: a randomised controlled trial

Study objectives
Does preoperative oral gabapentin and midazolam attenuate the stress response of tracheal intubation in breast cancer patients?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of National Cancer Institute, Cairo University, 01/03/2017, ref: 201617009.2p

Study design

Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Modified radical mastectomy under general anaesthesia

Interventions
Patients are randomised into two groups:
1. Oral gabapentin 800 mg plus 7.5 mg midazolam
2. Oral gabapentin 800 mg
Both drugs are given 90 min prior to surgery and patients are followed up to 24 hours postoperatively

Intervention Type

Primary outcome measure
1. Heart rate measured by electrocardiogram and pulse oximetry
2. Blood pressure measured by non invasive blood pressure monitor
Measured at baseline and at 0, 1, 3, 5, 10, 15 and 30 minutes of intubation

Secondary outcome measures
1. Sedation measured using Ramsay Sedation Scale
2. Side effects (e.g. nausea or vomiting) recorded by physician staff
Recorded over 24 h postoperatively

Overall study start date
15/02/2017

Completion date
08/06/2017

Eligibility

Key inclusion criteria

1. ASA1 or 2 patients
2. Between 18 to 65 years of age
3. Undergoing modified radical mastectomy under general anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60 patients in the two groups

Key exclusion criteria
1. Allergy to gabapentin or midazolam
2. Severe renal or liver insufficiency
3. Patient refusal

Date of first enrolment
15/02/2017

Date of final enrolment
15/05/2017

Locations

Countries of recruitment
Egypt

Study participating centre
National Cancer Institute, Cairo University
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type
University/education

Funder Name
National Cancer Institute, Cairo University

Alternative Name(s)
NCI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Egypt

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal

Intention to publish date
08/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ahmed Bakir (ahmed_bakir77@yahoo.com)

IPD sharing plan summary

Available on request