

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

<b>Submission date</b> 09/03/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/03/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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****Organisation**

National Cancer Institute, Cairo University

**Sponsor details**

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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