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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
09/03/2017	No longer recruiting	☐ Protocol
Registration date	Overall study status	<ul><li>Statistical analysis plan</li></ul>
20/03/2017	Completed	Results
Last Edited	st Edited Condition category	Individual participant data
20/03/2017	Surgery	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 ahmed bakir77@yahoo.com

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Ahmed Bakir

#### Contact details

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# Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Prevention

# 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(s)

- 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

## Key secondary outcome(s))

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

#### 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

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

**Female** 

#### 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

#### **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**

# 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

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes