ISRCTN48329522 https://doi.org/10.1186/ISRCTN48329522

Perioperative Duloxetine and Etoricoxib improve postoperative pain

Submission date
17/06/2017

Recruitment status
No longer recruiting

Registration date
19/06/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Having spinal surgery requires a lot of recovery time. Usually patients who undergo surgery need medication to help them recover and control any after surgery pain. There are a variety of medications that can be used to help treat patients. Some suggestions for medications to use include duloxetine (which is used to treat anxiety, depression, neurological pain) as well as etoricoxib (an anti-inflammatory (swelling) painkiller). It can be sometimes difficult for healthcare workers to figure out what the best combination of medications is most effective and provides patients with the least amount of side effects while still improving their pain symptoms. The aim of this study is to find the best regimen of drugs for the postoperative (after surgery) analgesia (pain prevention) for patients undergoing spinal surgeries in order to improve patient satisfaction of their postoperative care and to provide them with less side effects from medication after the surgery.

Who can participate?
Adults patients aged 18 and older who are having spinal surgery.

What does the study involve?
Participants are randomly allocated to one of four groups. Those in the first group receive a capsule containing a placebo (dummy drug) and two placebo tablets an hour before surgery and then again 24 hours later. Those in the second group receive a capsule a placebo and two etoricoxib tablets an hour before surgery and then again 24 hours later. Those in the first group receive a capsule containing duloxetine and two placebo tablets an hour before surgery and then again 24 hours later. Those in the fourth group receive a capsule containing duloxetine and two etoricoxib tablets an hour before surgery and then again 24 hours later. Patients then have their surgery as per standard practice. Half an hour after their anaesthesia has worn off and then two, four, six, 12, 24 and 48 hours later, participants are asked to rate their pain levels. Their satisfaction with the treatment they received and pain killer use is also recorded.

What are the possible benefits and risks of participating?
Participants may benefit from being more satisfied with their surgery and less side effects from drugs after the surgery. There are no notable risks with participating however there are risks with any medication and this should be monitored.

Where is the study run from?
Minia University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
April 2015 to May 2017

Who is funding the study?
Investigator initiated and funded (Egypt)

Who is the main contact?
Mr Josef Zekry Attia

Contact information

Type(s)
Scientific

Contact name
Mr Josef Zekry Attia

ORCID ID
http://orcid.org/0000-0003-4842-231X

Contact details
Faculty of Medicine
Al-Minia University
Main Road
Shalaby Land - Menia
Al-Minia
Egypt
61111
+20 10 00 427407
josefzekry2@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7

Study information

Scientific Title
Perioperative Duloxetine and Etoricoxib to improve postoperative pain after lumbar laminectomy: A randomized, double-blind, controlled study

Study objectives
Perioperative Duloxetine and Etoricoxib given together are more effective than when given individually at reducing postoperative pain after lumbar laminectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee at Faculty of Medicine Minia university, 01/05/2015, ref: 1-5-2015

Study design
Four-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Postoperative pain after laminectomy surguries

Interventions
Patients admitted to the hospital are randomised using computer-generated random numbers with closed-sealed envelopes into one of the four groups of 30 patients.

Group 1: Participants receive a placebo capsule + two placebo tablets one hour before surgery and again 24 hours later
Group 2: Participants receive a placebo capsule + 90 mg etoricoxib tablets one hour before surgery and again 24 hours later
Group 3: Participants receive a 60 mg duloxetine capsule + two placebo tablets one hour before surgery and again 24 hours later
Group 4: Participants receive a 60 mg duloxetine capsule + two 90 mg etoricoxib tablets one hour before surgery and again 24 hours later

Participants in all groups undergo surgery as per standard practice.

Participants in all groups are asked to rate their pain levels 30 minutes after the end of anesthesia and two, four, six, 12, 24 and 48 hours post-operatively. In addition, patient satisfaction and pain killer use is also assessed 24 and 48 hours after surgery.

Intervention Type
Other

Primary outcome measure
Pain is measured using pain assessment measures and questions 30 minutes after the end of anesthesia and two, four, six, 12, 24 and 48 hours post-operatively

Secondary outcome measures
1. The time to first rescue analgesic is routinely 24h and 48h postoperatively
2. Total morphine consumption is measured by calculating the doses at 24 and 48 hours post-operatively
3. Side effects, including headache, rash, nausea, vomiting, dizziness and drowsiness are recorded. The severity of postoperative nausea and vomiting (PONV) is graded on a four-point ordinal scale
4. Patient satisfaction is measured using a numerical rating scale (NRS) at 24 hours post-operatively

Overall study start date
01/04/2015

Completion date
01/05/2017

Eligibility

Key inclusion criteria
1. Patients with an ASA physical status of I, II and III scheduled for single level lumbar spinal disc prolapsed surgery
2. Can provide written informed consent
3. Aged between 18 and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
131 consecutive patients who met the inclusion criteria were allocated for the study . Eleven patients refused to participate. Therefore, 120 patients were randomized and included in the study. Characteristics of patients and surgical procedures for each group

Total final enrolment
120

Key exclusion criteria
1. History of allergic reaction to any of the study drugs
2. History of drug or alcohol abuse
3. Abnormal renal or liver function tests.
4. Patients using antidepressants who did not stop taking them two weeks before surgery
5. Patients with previous cervical surgeries, psychiatric disorders and patients receiving opioid analgesic medications within 24 hours preoperatively

Date of first enrolment
01/05/2015

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
Egypt

Study participating centre
Minia University Hospital
Corniche El Nil
El Corniche El Menia
Menia Governorate
Minia
Egypt
61111

Sponsor information

Organisation
Al-Minia University

Sponsor details
Faculty of Medicine
Main Road
Shalaby Land - Menia
Al-Minia
Egypt
61111
+20 86 23 42584
dean.med@mu.edu.eg

Sponsor type
University/education

Website
http://www.minia.edu.eg/med/

ROR
https://ror.org/02hcv4z63

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication of the research is planned to be after registering the clinical trial as soon as possible.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from josefzekry2@yahoo.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/12/2017	26/11/2020	Yes	No