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Preventing postoperative nausea and vomiting - a quality improvement project

Submission date
17/02/2020

Recruitment status
No longer recruiting

Registration date
26/02/2020

Overall study status
Completed

Last Edited
23/06/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The percentage of patients experiencing postoperative nausea and vomiting (PONV) is stagnating despite the availability of evidence-based international guidelines. This might be due to lack of adherence to actions to prevent PONV by using adequate preventative medication in the pre- and intra-operative period. The researchers think that adherence to the guideline can be improved with a multifaceted quality improvement intervention consisting of clinical lessons, personalized feedback, group feedback, and installation of reminders in print (posters) and integrated in the electronic health record (EHR) workflow. Furthermore, elements of clinical decision support (best practice advisories) will be added to the clinicians' workflow.

Who can participate?
EHR data of all adult patients scheduled for elective, non-cardiothoracic surgery during the study period will be used for data analysis. Data from patients who will be transferred to an ICU postoperatively will be excluded.

What does the study involve?
The study involves interventions to improve adherence to the PONVguideline with the focus on prevention of PONV. The interventions include organising clinical lessons for healthcare providers, placing reminders (posters), adding best practice advisories to the electronic health record workflow combined with automatic reminders and giving group feedback (email) as well as personalized feedback, based on advances of the intervention. Results are compared before and after implementing the intervention.

What are the possible benefits and risks of participating?
Participants may benefit from better prevention of PONV, resulting in less PONV after surgery. No risks are expected from the study.

Where is the study run from?
University Medical Center Groningen (The Netherlands)

When is the study starting and how long is it expected to run for?
October 2018 to February 2020 (updated 23/06/2020, previously: March 2020)

Who is funding the study?
University Medical Center Groningen (The Netherlands)

Who is the main contact?
Dr Peter Meyer
p.meyer@umcg.nl

Contact information

Type(s)
Scientific

Contact name
Dr Peter Meyer

Contact details
Principal Investigator
Hanzeplein 1
Groningen
Netherlands
9700RB
+31 (0)503616161
p.meyer@umcg.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
METc2018/670

Study information

Scientific Title
Improvement of postoperative nausea and vomiting prophylaxis by implementing a multifaceted quality improvement intervention

Study objectives
Adherence to postoperative nausea and vomiting (PONV) prophylaxis can be influenced by a multifaceted intervention, using different strategies. Addition to the teaching of healthcare professionals, the implementation of reminders in the electronic healthcare environment and personalized feedback can improve pre- and intra-operative prophylaxis of postoperative nausea and vomiting.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The study qualified for institutional review board exception status ("waiver of consent") on 11/12/2018, UMCG (University Medical Center Groningen) institutional review board (Medical Ethics Review Board, PO Box 30 001, 9700 RB Groningen, The Netherlands; +31 (0)50 361 42 04; metc@umcg.nl), ref: METc 2018/670

Study design
Observational single-center before-after study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Postoperative nausea and vomiting

Interventions
A multifaceted quality improvement intervention is carried out. The intervention in this project consists of organising clinical lessons for healthcare providers, placing reminders (posters), adding best practice advisories to the electronic health record workflow combined with automatic reminders and giving group feedback (email) as well as personalized feedback, based on advances of the intervention. An interrupted time-series design will be used to compare results before and after implementing the multifaceted intervention.

The interventions started in August 2019. Clinical lessons, group feedback, and personalized feedback still are active. Advances in EHR software went online 15/09/2019 and are active since. As this study relates to a quality improvement program, the effects of the interventions will be monitored continuously. If effects appear unsatisfactory, interventions will be adjusted. (e.g. best practice advisories will be displayed more prominently by means of pop-up screens). The monitoring of the control cohort started in week 6, 2019. According to the start of interventions in August 2019, follow-up began in week 33, on 12 August. The total duration of follow-up has not been determined yet, as this project has to be seen as a PDCA-cycle. Regarding an upcoming publication, follow-up until week 9, 2020 will be taken into account.

Intervention Type
Behavioural

Primary outcome(s)
Percentage of patients with completely filled in preoperative PONV risk scores (Apfel PONV Simplified Risk Scoring System). The weekly change of the percentage of filled in PONV risk scores will be displayed as a run chart and slopes will be compared between the pre- and post-intervention period.

Key secondary outcome(s))
The weekly change will be displayed as a run chart and slopes will be compared between the pre- and post-intervention period:
1. Percentage of patients with complete adherence to pharmaceutical prophylaxis according to

individual risk score
2. Percentage of patients receiving therapeutic anti-emetics on POD 0 and POD 1
3. Percentage of patients reporting clinically important PONV, measured by the PONV Intensity Scale

Completion date
29/02/2020

Eligibility

Key inclusion criteria
Adult patients scheduled for elective surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pediatric cases
2. Cardiothoracic surgery
3. Patients who will be admitted to ICU postoperatively

Date of first enrolment
04/02/2019

Date of final enrolment
29/02/2020

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen (UMCG)
Hanzeplein 1
Groningen
Netherlands
9700RB

Sponsor information

Organisation
University Medical Center Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

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 Peter Meyer (p.meyer@umcg.nl).

IPD sharing plan summary
Available on request