ISRCTN67177877 https://doi.org/10.1186/ISRCTN67177877

The association of cognitive dysfunction with CRP, cortisol, insulin, glucose and administered anesthesia type in total knee arthroplasties

Submission date
11/11/2017

Recruitment status
No longer recruiting

Registration date
16/11/2017

Overall study status
Completed

Last Edited
15/11/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Total knee arhtroplasty (TKA) or total knee replacements are a surgical procedure that replaces parts of the knee with metal and plastic joins. With the increasing age of the population, the amount of TKA has increased considerably. TKA is a very effective surgery for patients because they have favorable surgical outcomes as they noticeably lessen pain and enhances physical function. But like all operations, TKA have their own complications like thromboembolism (blood clots that forms and can plug the lungs, brains, kidneys, etc), cardiac arrhythmia (irregular heartbeat), pneumonia (inflammation of the lungs), pain, delirium (confusion) and postoperative cognitive dysfunction (POCD). POCD is one of the most important problems occurring after the TKA operation. POCD disturbs cognitive (mental) function, like, memory, attention, orientation, and concentration. There is research that says increases in hospital stay can cause functional damage, morbidity (diseases and illness), diminish in quality of life significantly. The exact causes behind the development of POCD are uncertain. The incidence of complications associated with TKA can vary with the type of anesthesia used in the surgery, such as general anesthesia that causes the patient to be unconscious and regional anesthesia that numbs a part of the body only. There have been conflicting results in terms of the effect of the anesthesia technique and POCD. The aim of this study is to investigate if the the amount of POCD changes with the type of anesthetic technique used.

Who can participate?
Adults aged 18-90 years old who are scheduled to undergo TKA.

What does the study involve?
Participants complete a questionnaire a day before their surgery. Participants are then randomly allocated to one of two groups. Participants in the first group receive the general anesthesia and then receive the surgery. Participants in the second group receive regional anesthesia that numbs a certain part of the body but does not make the person unconscious. Participants provide blood samples 15 before anesthesia, and at three and 24 hours after their surgeries. Participants repeat the questionnaire seven and 30 days after the procedure.

What are the possible benefits and risks of participating?
There are no direct benefits. There will be no additional risks to our patients because the anaesthetic techniques we apply are routine interventions for anaesthesia. There may be some mild discomfort when providing blood samples. The interviews with the patients are short and are harmless to the patients.

Where is the study run from?
Ahi Evran University, AEU (Turkey)

When is the study starting and how long is it expected to run for?
December 2016 to October 2017

Who is funding the study?
Ahi Evran University, AEU (Turkey)

Who is the main contact?
Dr Ipek Saadet Edipoglu

Contact information

Type(s)
Scientific

Contact name
Dr Ipek Saadet Edipoglu

ORCID ID
http://orcid.org/0000-0002-3510-5991

Contact details
Department of Anesthesiology
Suleymaniye Obstetrics & Pediatrics Training and Research Hospital
Istanbul
Türkiye
34020

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017-01/01

Study information

Scientific Title

The association of cognitive disfunction with crp, cortisol, insulin, glucose and administered anesthesia type in total knee arthroplasties: A randomised controlled trial

Study objectives
The aim of this study is to investigate if the incidence of postoperative cognitive dysfunction changes according to the anesthetic technique preferred (general or regional). The secondary study aim is to detect the association of the biomarkers of surgical stress (CRP, insulin, cortisol) and anesthetic technique applied (general or regional).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ahi Evran University ethical committee, 03/01/2017, ref: 2017-01/01

Study design
Single center randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Postoperative cognitive dysfunction

Interventions
Participants are randomised with computer software program for block randomization and divided into general or regional anesthesia group. If a patient had a contradiction for their anesthesia type randomized, they are excluded from the study.

The participants in each group differ in terms of the anaesthetic technique they got. General anesthesia affects the entire body and makes the person unconscious. The unconscious person is completely unaware of what is going on and does not feel pain from the surgery or procedure. Our general anesteshia group patients have hypnotics (Propofol) and opioids (fentanyl) and muscle relaxants (rocuronium) for their induction of anesthesia. Regional anesthesia numbs a limited part of the body and prevents patients from feeling pain and does not make the person unconscious. Our regional anesthesia patients have 15 mg of spinal heavy bupivacaine in their intrathecal space.

Routine general anesthesia induction for TKA involved using 100% oxygen, followed by an induction with Propofol (2 mg kg-1) and rocuronium (0.6 mg kg-1). Anesthesia was maintained with sevoflurane (2%) and a mix of 50% O2 and 50% nitrous oxide. Routine regional anesthesia administration involved a single shot of 2.8 ml hyperbaric bupivacaine (0.5%) into the subarachnoid space of the L3-L4 intervertebral space. All patients had same pain treatment with morphine patient controlled analgesia (PCA). Rescue pain treatment is used with tramadol and additional morphine when necessary.

Blood samples from all participants are included in the study. Cortisol, insulin, CRP and blood glucose levels are tested. Blood samples are taken 15 minutes before anesthesia induction for base results, intraoperative 1th hour, postoperative 3rd hour and postoperative 24th hour. The neurocognitive tests are achieved by one of our anesthesiology consultant who were under the supervision of a psychiatrist. Mini mental test (MMS), The Cognitive Failure Questionnaire (CFQ), Auditory Verbal Learning Test (AVLT) and Stroop Interference Test (SIT) are applied by anesthetist one-day before operation (preoperative), seven-days after operation and 30-days after operation.

All participants have the same follow up. In the first postoperative day they have the same analgesic treatments (Patient controlled analgesia-PCA). They are assessed 7-days after and 30-days after with questionnaires. No additional intervention or follow up is required.

Intervention Type
Procedure/Surgery

Primary outcome measure
Incidence of postoperative cognitive dysfunction changes is measured using the Mini mental test (MMS), The Cognitive Failure Questionnaire (CFQ), Auditory Verbal Learning Test (AVLT) and Stroop Interference Test (SIT) at 1st preoperative, 7th and 30th postoperative days.

Secondary outcome measures
The association of the biomarkers of surgical stress (CRP, insulin, cortisol glucose) and anesthetic technique applied (general or regional) is measured using routine kits at before 15 minutes before anesthesia induction (preoperative), 1st hour during operation, 3rd and 24th hours after operation.

Overall study start date
03/12/2016

Completion date
04/10/2017

Eligibility

Key inclusion criteria
1. Patients scheduled for elective total knee arthroplasty (TKA)
2. Aged <90
3. BMI<40
4. Patients with a Mini Mental Score>15
5. Unilateral cases

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Patients >90
2. Emergent cases
3. Patients with prior psychiatric or neurologic disorders
4. Patients using steroid medications
5. Uncontrolled diabetes

Date of first enrolment
04/01/2017

Date of final enrolment
05/09/2017

Locations

Countries of recruitment
Türkiye

Study participating centre
Ahi Evran University
Istanbul
Türkiye
40100

Sponsor information

Organisation
Ahi Evran University Medical Faculty

Sponsor details
Bağbaşı Mahallesi
Şht. Sahir Kurutluoğlu Cd.

Kırsehir
Türkiye
40100

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05rrfpt58

Funder(s)

Funder type
University/education

Funder Name
Ahi Evran Üniversitesi

Alternative Name(s)
Ahi Evran University, AEU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Türkiye

Results and Publications

Publication and dissemination plan
We planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/10/2018

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. Ipek S. Edipoglu. dripeks@yahoo.com.

IPD sharing plan summary
Available on request