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# 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

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# Additional identifiers

### Protocol serial number
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

## Study type(s)
Diagnostic

## 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(s)
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.

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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

**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

## 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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |