

# Effect of different musical types on shock wave lithotripsy for kidney stone treatment

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/07/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/07/2018	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Kidney stones are solid crystals of waste products from the blood that can build up in the kidneys. A treatment for kidney stones is extracorporeal shock wave lithotripsy (SWL), which is where shock waves from outside the body are used to break apart the kidney stones so that eventually, they are small enough to pass through the urine. SWL can cause pain and anxiety for patients. The aim of this study was to investigate the effects of listening to different music types during SWL on the patient's pain control, anxiety level, and satisfaction.

### Who can participate?

Adults who have a radiopaque kidney stone 10-20 mm in diameter localized in the renal pelvis or ureteropelvic junction

### What does the study involve?

All patients will receive SWL, but will be randomised into five different groups:

1. Group 1 wears no headphones and listens to no music during SWL
2. Group 2 wears headphones but listens to no music during SWL
3. Group 3 listens to Turkish art music with headphones during SWL
4. Group 4 listens to Western classical music with headphones during SWL
5. Group 5 listens to music of their choice during SWL

Patients will then be asked to provide pain and anxiety scores after treatment.

### What are the possible benefits and risks of participating?

The possible benefit of participating is reduced levels of pain and anxiety associated with SWL treatment. There only risks to participants are the standard risks associated with SWL treatment.

### Where is the study run from?

Department of Urology, Faculty of Medicine, Adiyaman University, Adiyaman, Turkey.

### When is the study starting and how long is it expected to run for?

May 2015 to January 2018

Who is funding the study?

The study is self-funded:

1. Dr Ali Çift (Turkey)
2. Dr Alper Gök (Turkey)

Who is the main contact?

1. Dr. Ali Çift, alicift@mynet.com
2. Dr. Alper Gök, alper\_gok@hotmail.com

## Contact information

### Type(s)

Scientific

### Contact name

Dr ALPER GÖK

### ORCID ID

<https://orcid.org/0000-0001-6874-4151>

### Contact details

ayvalı mahallesi mecit caddesi mutlu sitesi 1a/5

Mutlu sitesi

Ankara

Türkiye

06000

+905326031181

alper\_gok@hotmail.com

## Additional identifiers

### Protocol serial number

1

## Study information

### Scientific Title

Effect of different musical types on patient's relaxation, anxiety and pain perception during Shock Wave Lithotripsy

### Study objectives

Is there effect of listening different music types during extracorporeal shock wave lithotripsy on the patient's pain control, anxiety level, and satisfaction?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

University of Adiyaman ethics board, 22/06/2016, 2016/5-5

## **Study design**

Observational prospective randomised cohort study

## **Primary study design**

Observational

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Kidney stones

## **Interventions**

Shock Wave Lithotripsy. Participants were randomly divided into the study groups. Brief summary of methodology: The patients were divided into five groups by randomizing prospectively. A total of 150 patients (30 participants in each group) who underwent first-session SWL were included in the study. Demographic data related to patients and procedure, State-Trait Anxiety Inventory-State Anxiety (STAI-SA), Visual Analog Scale (VAS) scores, willingness to repeat procedure (0: never 4: happily), and patient satisfaction rates (0: poor 4: excellent) were recorded immediately after the procedure.

Participants were randomly divided into five study groups:

1. Group 1 wore no headphones and no music was played during extracorporeal shock wave lithotripsy (ESWL)
2. Group 2 wore headphones but no music was played during ESWL
3. Group 3 listened to Turkish art music with headphones during ESWL
4. Group 4 listened to Western classical music with headphones during ESWL
5. Group 5 listened to music of the participant's choice with headphones during ESWL

## **Intervention Type**

Mixed

## **Primary outcome(s)**

The following were assessed immediately after the extracorporeal shock wave lithotripsy procedure:

1. Anxiety, assessed using the State-Trait Anxiety Inventory-State Anxiety form (STAI-SA)
2. Pain, assessed using the Visual Analog Scale (VAS)

## **Key secondary outcome(s)**

The following were assessed immediately after the extracorporeal shock wave lithotripsy procedure:

1. Willingness to repeat procedure, assessed on a scale of 0-4 where 0 indicates "never", 1 indicates "very little", 2 indicates "little", 3 indicates "much" and 4 indicates "happily"
2. Patient satisfaction, assessed on a scale of 0-4 where 0 indicates "poor", 1 indicates "very little", 2 indicates "little", 3 indicates "much" and 4 indicates "excellent"

## **Completion date**

30/01/2018

## **Eligibility**

**Key inclusion criteria**

1. Radiopaque stone 10-20 mm in diameter, localised in the renal pelvis or ureteropelvic (UP) junction
2. Aged 18 years of old

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Previous treatment with shock wave lithotripsy
2. Ureteral stents
3. Renal colic

**Date of first enrolment**

01/07/2016

**Date of final enrolment**

30/11/2017

**Locations****Countries of recruitment**

Türkiye

**Study participating centre**

Department of Urology, Faculty of Medicine, Adiyaman University, Adress: Yunus Emre Mahallesi, 1164. Sk. No:13, 02000 Merkez/Adiyaman, Turkey.

Adress: Yunus Emre Mahallesi, 1164. Sk. No:13, 02000 Merkez/Adiyaman Merkez/Adiyaman Adiyaman  
Türkiye  
02000

**Sponsor information**

**Organisation**

University of Adiyaman, Adiyaman, Turkey

**ROR**

<https://ror.org/02s4gkg68>

**Funder(s)****Funder type**

Not defined

**Funder Name**

None

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated and analysed during the current study are available upon request from Dr. Ali Çift by e-mail ([alificent@mynet.com](mailto:alificent@mynet.com)). All the data is available in Excel format for all researchers whenever wanted. Written informed consents were obtained from all patients for participating to this study. There are no ethical or legal restrictions.

**IPD sharing plan summary**

Available on request