ISRCTN85279715 https://doi.org/10.1186/ISRCTN85279715

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

Submission date
14/07/2018

Recruitment status
No longer recruiting

Registration date
29/07/2018

Overall study status
Completed

Last Edited
30/07/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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, Adıyaman University, Adıyaman, 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
http://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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Adıyaman ethics board, 22/06/2016, 2016/5-5

Study design
Observational prospective randomised cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the following contact details to request a participant information sheet: alicift@mynet.com

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 measure
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)

Secondary outcome measures
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"

Overall study start date
01/05/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Previous treatment with shock wave lithotropsy
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, Adıyaman University, Adress: Yunus Emre Mahallesi, 1164. Sk. No:13, 02000 Merkez/Adıyaman, Turkey.
Adress: Yunus Emre Mahallesi, 1164. Sk. No:13, 02000 Merkez/Adıyaman Merkez/Adıyaman
Adıyaman
Türkiye
02000

Sponsor information

Organisation
University of Adıyaman, Adıyaman, Turkey

Sponsor details
Yunus Emre Mahallesi, 1164. Sk. No:13, 02000 Merkez/Adıyaman Merkez/Adıyaman
Adıyaman
Türkiye
02000
+904162161015
alper_gok@hotmail.com

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02s4gkg68

Funder(s)

Funder type
Not defined

Funder Name
None

Results and Publications

Publication and dissemination plan
We intend to publish in BMC Urology.

Intention to publish date
01/08/2018

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 (alicift@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