

Can pain and anxiety be reduced in cystoscopy?

Submission date 04/09/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/09/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/09/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Flexible cystoscopy is a routine outpatient procedure used to examine the bladder. Although it is generally safe, many patients feel anxious and experience discomfort during the procedure. This study is testing whether two simple, non-invasive methods, showing patients a short educational video before the procedure and using virtual reality (VR) distraction during the procedure, can make the experience less stressful and less painful.

Who can participate?

Adult patients who need flexible cystoscopy at Ümraniye Training and Research Hospital

What does the study involve?

Patients will be randomly assigned to one of four groups: (1) video only, (2) video + VR, (3) VR only, and (4) routine care without video or VR. The video explains the procedure in simple terms, while the VR headset shows calming 360° nature scenes.

The study will measure patients' long-term tendency to experience anxiety and their current state of anxiety using questionnaires before and immediately after the procedure. Pain intensity will be assessed during cystoscopy using a scale. All procedures will be performed by experienced urologists under local anaesthesia, and data will be collected by a second physician.

What are the possible benefits and risks of participating?

The results of this study will help determine whether video education and VR distraction are effective in reducing anxiety and pain during flexible cystoscopy, and may guide improvements in patient care.

No risks given at registration.

Where is the study run from?

Ümraniye Training and Research Hospital, Department of Urology.

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

October 2024 to January 2025

Who is funding the study?
Ümraniye Training and Research Hospital, Department of Urology. (no external funding)

Who is the main contact?
Dr Murat Beyatlı, muratbeyatli_90@hotmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Effects of pre-procedural video education and intra-procedural virtual reality on anxiety and pain during flexible cystoscopy: a randomized controlled trial

Acronym

VR-CYSTO

Study objectives

To evaluate whether pre-procedural video education and intra-procedural virtual reality distraction reduce anxiety and pain compared to standard care in patients undergoing flexible cystoscopy.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 07/11/2024, Ümraniye Training and Research Hospital Ethics Committee (Elmalıkent Neighborhood Adem Yavuz Street No:1, Ümraniye/Istanbul, 34760, Türkiye; +90 (0216) 632 18 18 /11 64; not@available.com), ref: 370

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life, Efficacy

Health condition(s) or problem(s) studied

Procedural anxiety and pain in patients undergoing flexible cystoscopy

Interventions

Randomisation is 1:1:1:1 using computer-generated allocation.

Participants are randomised into four parallel arms:

1. Pre-procedural educational video + VR headset during cystoscopy;
2. Educational video only;
3. VR headset only;
4. Control group receiving standard care (no video, no VR).

The video lasts ~3 minutes and explains the cystoscopy procedure. The VR headset shows neutral, relaxing content during the procedure until completion (average 5–10 minutes).

Intervention Type

Behavioural

Primary outcome(s)

1. Pain intensity measured using the Visual Analogue Scale (VAS, 0–10) during the cystoscopy procedure
2. State anxiety measured using the State-Trait Anxiety Inventory – State (STAI-S) at baseline (before cystoscopy) and immediately after the procedure

Key secondary outcome(s)

1. Trait anxiety measured using the State-Trait Anxiety Inventory – Trait (STAI-T) at baseline only, before the procedure.
2. Adverse events, defined as any complications or side effects observed during or after cystoscopy (e.g., dizziness, nausea, vasovagal symptoms), measured using medical records at one timepoint

Completion date

30/01/2025

Eligibility

Key inclusion criteria

1. Age \geq 18 years
2. Indication for flexible cystoscopy
3. Adequate cognitive function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

240

Key exclusion criteria

1. Current use of anxiolytics, antidepressants, or opioids
2. Prior history of cystoscopy
3. Significant cognitive or psychiatric disorders
4. Severe hearing/visual impairment preventing video or VR use
5. Active urinary tract infection or chronic bladder pain
6. History of severe allergic reaction to local anesthetics
7. Pregnancy

Date of first enrolment

08/11/2024

Date of final enrolment

30/01/2025

Locations**Countries of recruitment**

Türkiye

Study participating centre

Ümraniye Training and Research Hospital, Department of Urology
Elmalıkent Mahallesi Adem Yavuz Cad. No:1 Ümraniye / İstanbul
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Türkiye
34764

Sponsor information

Organisation

Ümraniye Training and Research Hospital

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Ümraniye Training and Research Hospital

Results and Publications

Individual participant data (IPD) sharing plan

De-identified or anonymised datasets of individual participant data (IPD) will be made available from the corresponding author (Murat Beyatlı, muratbeyatli_90@hotmail.com) on reasonable request after publication of the study results. Data will be shared for academic purposes only, in anonymised form, without any information that could identify individual participants.

IPD sharing plan summary

Available on request