ISRCTN14221501 https://doi.org/10.1186/ISRCTN14221501

Effect of ketorolac and dexamethasone injections on pain after renal stent surgery

Submission date	Recruitment status	[X] Prospectively registered
04/03/2024	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
06/03/2024	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
06/03/2024	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Many patients suffer from kidney stone surgery particularly the insertion of a ureteral stent (a thin tube inserted into the ureter). After stent removal, a high percentage of patients experience substantial kidney pain. The aim of this study is to investigate whether the administration of ketorolac and dexamethasone during stent removal can decrease the level of kidney pain.

Who can participate?:
Adult patients aged 18 to 85 years who undergo stent placement for kidney/ureteral stones

What does the study involve?:
Patients will be randomly placed into three study groups: the ketorolac group, which will receive an intramuscular injection (into a muscle) of ketorolac and an intramuscular injection of 0.9% normal saline within 30 minutes of stent removal, the ketorolac and dexamethasone group, which will receive an intramuscular injection of ketorolac and dexamethasone within 30 minutes of stent removal, and the placebo group, which will receive two intramuscular injections of 0.9% normal saline. All patients will be assessed 1 and 7 days after stent removal.

What are the possible benefits and risks of participating?
The possible benefits are decreased level of kidney pain and fewer missed days of work after stent removal. The possible risks are injection site reactions and infections.

Where is the study run from?
Erfain Hospital (Iran)

When is the study starting and how long is it expected to run for?
December 2023 to April 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mohammadreza Noroozi, noroozi.mr@cfbcr.org

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CFBCR.REC.2023019

Study information

Scientific Title
Efficacy and safety of intramuscular ketorolac and dexamethasone for preventing renal colic post stent removal: a randomized triple-blind, placebo-controlled clinical trial

Study objectives
Intramuscular ketorolac and dexamethasone alleviate renal pain after stent removal

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/12/2023, Ethics Committee of Center for Fundamental, Biomedical and Clinical Research (Shahid Riazi Bakhshayesh St. Saadat Abad, Tehran, 1945784320, Iran; +98 (0) 2161323389; vcr@cfbcr.org), ref: CFBCR.REC.2023019

Study design

Randomized triple-blind placebo-controlled clinical trial

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Preventing renal colic post stent removal

Interventions
Patients will be randomized into three study groups (block randomization with a block size of 6):
1. Ketorolac group (K group), which will receive an intramuscular injection of ketorolac (ketorolac tromethamine, 30 mg in 1 ml) and an intramuscular injection of 1 ml of 0.9% normal saline within 30 minutes of stent removal
2. Ketorolac and dexamethasone group (KD group), which will receive an intramuscular injection of ketorolac (Ketorolac tromethamine, 30 mg in 1 ml) and dexamethasone (dexamethasone phosphate, 8 mg in 2 ml) within 30 minutes of stent removal
3. Placebo group (P group), which will receive two intramuscular injections of 1 ml of 0.9% normal saline.

A blinded, qualified nurse performed the injections. All patients will be assessed 1 and 7 days after stent removal.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Ketorolac tromethamine, dexamethasone phosphate

Primary outcome(s)
Pain measured using the visual analogue score (VAS) on day 1 and day 7

Key secondary outcome(s))
1. Opioid use, measured by the number of patients with any opioid use on day 1
2. Urgent pain-related clinical encounters, measured by the number of pain-related clinical encounters in the emergency department since the stent removal
3. Subjective renal colic symptoms, measured by the number of patients that experienced renal colic symptoms since the stent removal to day 7
4. Missed days of work, measured by the number of missed days of work since the stent removal to day 7
5. Injection complications, measured as the number of patients with any injection complication since the stent removal to day 7

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Patients who underwent stent placement for renal/ureteral stones and returned for cystoscopical stent removal
2. Age between 20 and 85 years old
3. Providing informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
85 years

Sex
All

Key exclusion criteria
1. Absolute or relative contraindication to ketorolac or dexamethasone
2. Acute or chronic renal failure (estimated glomerular filtration rate <50)
3. History of GI bleeding or peptic ulcer disease
4. Elevated risk of bleeding including cerebrovascular bleeding, haemorrhagic diathesis, use of any anticoagulants, or any bleeding disorder
5. Systemic infections or cerebral malaria
6. Use of live or live-attenuated vaccines
6. Concurrent use of NSAIDs or corticosteroids
7. Pregnancy
8. Breastfeeding

Date of first enrolment
15/03/2024

Date of final enrolment
29/04/2024

Locations

Countries of recruitment
Iran

Study participating centre
Erfain Hospital
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Sponsor information

Organisation
Center for Fundamental Biomedical Clinical Research

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

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