

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

Submission date 04/03/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/03/2024	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Safety, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Condition

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

Pharmaceutical study type(s)

Not Applicable

Phase

Phase II

Drug/device/biological/vaccine name(s)

Ketorolac tromethamine, dexamethasone phosphate

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/12/2023

Overall study end date

30/04/2024

Eligibility

Participant inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Lower age limit

20 Years

Upper age limit

85 Years

Sex

Both

Target number of participants

174

Participant 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

Recruitment start date

15/03/2024

Recruitment end date

29/04/2024

Locations

Countries of recruitment

Iran

Study participating centre**Erfain Hospital**

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Sponsor information

Organisation

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Sponsor type

Research organisation

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact journal

Intention to publish date

01/08/2024

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