

Comparison of two analgesic combinations for reno-ureteral colic treatment

Submission date 04/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 04/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/08/2022	Condition category 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

Reno-ureteral colic happens when a stone gets lodged in your urinary tract, often in a ureter. The stone stretches and widens the area, causing intense pain.

The standard treatment consists of a painkiller (diclofenac) given directly via a vein, which is commonly combined with butylhyoscine. Such a combination lacks clinical evaluation in the literature, and a clinical practice guidelines suggest ketorolac and metamizole as second-line treatments. Given the complex behavior of reno-ureteral colic, the ketorolac and metamizole combination may represent a better clinical practice to benefit patients. The present study is aimed to evaluate the efficacy of ketorolac/metamizole versus diclofenac/butylhyoscine for reno-ureteral colic management.

Who can participate?

Patients with reno-ureteral colic and aged at least 18 years

What does the study involve?

Patients will be randomly allocated to a single dose of either ketorolac/metamizole or diclofenac /butylhyoscine, and will be monitored from baseline to 45 min.

What are the possible benefits and risks of participating?

The benefits include evidence-based management for reno-ureteral colic treatment, and the risks for such safe drugs might involve hypersensitivity to formulations.

Where is the study run from?

Instituto Mexicano del Seguro Social (Mexico)

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

September 2021 to September 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Dr Julieta Godoy-Caballero, godoyjulieta957@gmail.com

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

R-2021-3201-168

Study information

Scientific Title

Analgesic efficacy of ketorolac/metamizole versus diclofenac/butylhyoscine for reno- ureteral colic management in a primary-care hospital emergency service

Acronym

KMDB

Study objectives

Ketorolac/metamizole analgesic efficacy is similiar to diclofenac/butylhyoscine in reno-ureteral colic management

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/11/2021, IMSS Local Health Research Committee 3201 (Comite Local de investigacion en salud del IMSS 3201, 41 street, Mérida Yucatán, México; no telephone number provided; comite.eticainv@imss.gob.mx), ref: R-2021-3201-168

Study design

Single center interventional blinded randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Reno-ureteral colic management

Interventions

Participants will be randomized 1:1 to receive the intervention or the comparison treatment. This process will occur when the patient arrives at the Emergency service from the primary-care hospital and will be performed with sealed envelopes containing the written informed consent, the pain-scale questionnaires, and a colored mark indicating the treatment that should be given.

Patients in the intervention group will receive a single intramuscular dose of ketorolac (30mg) /metamizole (1g).

Patients in the comparison group will receive diclofenac (75mg)/ butylhyoscina (20mg). Patients are then monitored for 45 minutes.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ketorolac, metamizole, diclofenac, butylhyoscine

Primary outcome(s)

Pain is measured using a visual analogue scale (VAS) at baseline, 10, 20, and 45 min

Key secondary outcome(s)

The brief pain inventory (short form in Spanish) will be applied to assess the severity of pain and its impact on functioning at baseline

Completion date

20/09/2022

Eligibility

Key inclusion criteria

1. Aged 20 to 60 years
2. Clinical signs and symptoms of reno-ureteral colic

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Hypersensitivity to any of the tested drug formulations
2. Patients with severe reno- ureteral colic (with fever and chronic pain)
3. Grade III and IV renal insufficiency
4. Patients will be excluded if they have any pre-existing treatment that might interact with the tested drug
5. Patients will be excluded if they possess pre-existing digestive tube bleeding

Date of first enrolment

01/01/2022

Date of final enrolment

30/04/2022

Locations**Countries of recruitment**

Mexico

Study participating centre

Instituto Mexicano del Seguro Social

42 street, Serapio rendon

Mérida

Mexico

97285

Sponsor information**Organisation**

Mexican Social Security Institute

ROR

<https://ror.org/03xddgg98>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The database will be available upon reasonable request.

godoyjulietta957@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/03/2022	No	Yes
Protocol file		01/11/2021	10/03/2022	No	No