Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Pain Relieving Effect of Glycerol Trinitrate (GTN) in Renal Colic: a Randomized Placebo-Controlled Trial

Protocol summary

Study aim

Evaluation of pain relieving effect of GTN Glyceryl Trinitrate spray in patients referred to the emergency department (ED) due to renal colic pain

Design

This study will be a blind, randomized, placebo-controlled three-way trial.

Settings and conduct

This study will be performed in the internal ward of Shariati Hospital, Tehran, Iran. Patients entered the study after signing the informed consent form. Researchers will adhere to the Helsinki Declaration of Principles during the study.

Participants/Inclusion and exclusion criteria

Patients over 16 years of age, who are clinically diagnosed by an emergency physician with imaging (ultrasound or CT scan) to have renal colic and have a pain level higher than 5 on the VAS scale). The following will be considered as exclusion criteria: symptoms of peritoneal irritation, pregnancy and lactation, fever or hypotension; History of sildenafil, tadalafil, vardenafil, antihypertensive drugs, aspirin, antimuscarinic, alcohol, ergotamine, haloperidol or phenothiazine during the last 4 weeks,

Intervention groups

The intervention group receiving the GTN Glyceryl Trinitrate spray and the control group that will receive only the plasbo treatment.

Main outcome variables

Pain relief is defined as the reduction of VAS pain to less than 5. Therefore, the pain will be measured again in patients after 5 minutes, and if the VAS pain was still more than 5, the patient will receive another 30 mg of ketorolac injection. Pain will be re-estimated 30 minutes after this dose, and if the patient has a VAS pain score higher than 5, the next dose of ketorolac will be injected. Response to VAS treatment is defined as less than 5.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180428039443N2**
Registration date: **2021-04-06, 1400/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-06, 1400/01/17**
Update count: **0**

Registration date

2021-04-06, 1400/01/17

Registrant information

Name

Ahmad Reza Dehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-12, 1399/11/24

Expected recruitment end date

2021-09-20, 1400/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pain Relieving Effect of Glycerol Trinitrate (GTN) in Renal Colic: a Randomized Placebo-Controlled Trial

Public title
Pain Relieving Effect of Glycerol Trinitrate (GTN) in Renal Colic

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 16 years of age, who are clinically diagnosed by an emergency physician with imaging (ultrasound or CT scan) to have renal colic and have a pain level higher than 5 on the VAS scale). Patients who have treated themselves or had side effects from diseases such as gastrointestinal, heart, kidney or liver are not included. The following will be considered as exclusion criteria: symptoms of peritoneal irritation, pregnancy and lactation, fever or hypotension; History of sildenafil, tadalafil, vardenafil, antihypertensive drugs, aspirin, antimuscarinic, alcohol, ergotamine, haloperidol or phenothiazine during the last 4 weeks,

Exclusion criteria:
allergic reaction to GTN; Severe clinical anemia; Recent concussion or any damage to the central nervous system, malnutrition, hypothyroidism; Hypothermia; And drug abusers.

Age
From **16 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The random number sequences of volunteers are made by the Sealed Envelope | Randomization site. Using random quadrilateral blocks, the random chain is created at first by the number of sample volumes.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Because of the nature of the outcome of the disease (pain), blindness or blindness does not disclose the study. However, the final data for analysis will be coded and analyzed without the knowledge of the treatment group. Data collection authorities and those who evaluate the outcome, Data Safety and Monitoring Committee, and those who prepare the draft article, are kept blind to the studied groups.

Placebo
Used

Assignment
Parallel

Other design features
This study will be a blind, randomized, placebo-controlled three-way trial that will be performed in the internal ward of Shariati Hospital, Tehran, Iran. Patients entered the study after signing the informed consent form. Researchers will adhere to the Helsinki Declaration of Principles during the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Medical School, PourSina St., Tehran, 1417613151, Iran

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2021-01-29, 1399/11/10

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.1034

Health conditions studied

1

Description of health condition studied
Renal Colic

ICD-10 code
N23

ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description
Pain Relieving

Timepoint
Pain will be measured again in patients after 5 minutes, and if the VAS pain is still more than 5, the patient will receive another 30 mg of ketorolac injection. Pain will be re-estimated 30 minutes after this dose, and if the patient has a VAS pain score higher than 5, the next dose of ketorolac will be injected.

Method of measurement
Response to VAS treatment is defined as less than 5.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who receive, in addition to standard treatment Glycerol Trinitrate (GTN). GTN sprays contain 0.4 mg of trinitroglycerin.
Category
Treatment - Drugs

2

Description
Control group: Patients undergoing standard treatment and receiving placebo. Placebo sprays will contain exponents to have a similar odor to the patients receiving them until they look exactly the same. We will record the number for each package and content as a placebo or GTN spray.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Javad Seyedhosseini
Street address
Medical School, PourSina St., Tehran, 1417613151, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amir Esmaeil Saghafi nia
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ahmad Reza Dehpour
Position
Professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All patient information documented data without identification. The information entered will eventually be entered in the database of the database.

When the data will become available and for how long
Data will be available upon national and international patenting process completion of the study.

To whom data/document is available
All interested researchers

Under which criteria data/document could be used
There is no specific condition.

From where data/document is obtainable
Dr. Ahmad Reza Dehpour

What processes are involved for a request to access data/document
The procedure outlined by the Ethics Committee of Tehran University of Medical Sciences

Comments