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# A randomised controlled trial comparing spontaneous ureteric stone passage rates with tamsulosin versus placebo in the management of acute renal colic

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 30/09/2004 | Stopped | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/09/2004 | Stopped | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 28/03/2013 | Urological and Genital Diseases | [_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
N0234135766

## Study information

## Scientific Title

## Study objectives
Can tamsulosin, an alpha-1-adrenergic antagonist, be used in uncomplicated renal colic to improve spontaneous ureteric calculus passage rates.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Approval for the lead centre: Central and South Bristol Research Ethics Committee. Date of approval: 24/09/2004 (ref: 04/Q2006/88). All other centres obtained approval before recruitment of participants.
2. Medicines and Healthcare products Regulatory Agency (MHRA). Approval expected in May 2008.

## Study design
Randomised, double-blind, placebo-controlled, multi-centre trial.

## Primary study design
Interventional

## Study type(s)
Not Specified

## Health condition(s) or problem(s) studied
Urological and Genital Diseases: Acute renal colic

## Interventions
As of 28/03/2013 the trial status was changed to 'stopped' as the trial was closed in January 2011 due to recruitment issues.

Please note that, as of 11/04/2008, the anticipated start and end dates of this trial were updated from 01/06/2005 and 01/04/2007 to 01/05/2008 and 31/05/2010.

This study is proposed to be a prospective, randomised double blind placebo controlled clinical trial. The patients will be randomly allocated to receive tamsulosin or placebo for a maximum of 6 weeks during conservative treatment of renal colic. Patients will be regularly monitored for side effects, stone passage and analgesic use during this time period.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Tamsulosin

## Primary outcome(s)

Primary outcome measures amended as of 11/04/2008:
1. Spontaneous stone passage within 6 weeks
2. Early intervention due to complications

Primary outcome measures provided at time of registration:
1. The percentage of calculi passed spontaneously within 6 weeks
2. The mean time to spontaneous passage
3. The mean use of analgesia in the form of diclofenac (recommended first line analgesic)

### Key secondary outcome(s))
Added as of 11/04/2008:
The following will be assessed at the end of the trial, i.e. time of stone passage or 6 weeks if stone not passed:
1. Percentage of calculi passed spontaneously within six weeks
2. Mean time to spontaneous passage
3. Mean use of analgesia in the form of diclofenac

### Completion date
31/05/2010

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
The total sample size required to produce statistically significant results is 206 patients (103 to receive placebo). All patients with renal colic with a visible calculus on X-ray which has been confirmed to be present within the ureter on intravenous urogram (IVU) will be asked to participate.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### Key exclusion criteria
Patients will be excluded if pregnant, symptoms present for >14 days, evidence of infection or if they are already receiving treatment with tamsulosin or other calcium channel blocker.

### Date of first enrolment
01/05/2008

**Date of final enrolment**
31/05/2010

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Urology Department**
Bristol
United Kingdom
BS10 5NB

# Sponsor information

**Organisation**
Department of Health

# Funder(s)

**Funder type**
Government

**Funder Name**
North Bristol NHS Trust (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**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 |