

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

Submission date 30/09/2004	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 28/03/2013	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Kim Davenport

Contact details

Urology Department
North Bristol NHS Trust
Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB
DrKimDav@aol.com

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