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

Contact name

Dr Kim Davenport

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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

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 analogsic use during this time period.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Tamsulosin

Primary outcome measure

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)

Secondary outcome measures

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

Overall study start date

01/05/2008

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

206

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

England

United Kingdom

Study participating centre Urology Department

Bristol United Kingdom BS10 5NB

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

North Bristol NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration