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

Plain English Summary
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0234135766

Study information

Scientific Title

Study hypothesis
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

Condition
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 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

Overall study end date
31/05/2010

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Participant 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

Participant 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.

Recruitment start date
01/05/2008

Recruitment end date
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