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Spontaneous Urinary Stone Passage ENabled by Drugs

Submission date	Recruitment status	[X] Prospectively registered
14/04/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/08/2015	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
A kidney stone is a piece of solid material that forms in the kidney when minerals in the urine become very concentrated. If stones grow to sufficient size they can cause blockage of the ureter (the tube that carries urine from the kidney to the bladder) and can be very painful. They are a common cause of emergency hospital admission due to severe pain and requirement for pain relief, time off work and often repeated hospital admissions for treatment. Drugs that cause relaxation of the ureter can enhance the spontaneous passage of ureteric stones. The drugs Tamsulosin and Nifedipine can improve the passage of ureteric stones and the process is termed medical expulsive therapy (MET). This avoids the need for further treatment. The aim of this study is to determine the clinical effectiveness and cost-effectiveness of the use of Tamsulosin and Nifedipine in the management of ureteric stones.

Who can participate?
Patients aged 18-65 with a confirmed ureteric stone.

What does the study involve?
Participants will be randomly allocated to be treated with either Nifedipine, Tamsulosin or placebo (dummy) tablets. Participants will take one capsule orally per day for a maximum of 28 days and will be followed up by postal questionnaires sent from the trial office at 4 and 12 weeks after random allocation. In addition patients may be reviewed in clinic at 4 weeks after random allocation.

What are the possible benefits and risks of participating?
The potential benefits to participants are that the pain and discomfort caused by their ureteric stone will be relieved sooner and they may avoid additional treatment. There may be no personal benefit from taking part in the study as there is no guarantee that the MET therapy will be successful, but participants will be offered other treatments if symptoms get worse or do not improve. By taking part in the study participants will be directly helping in the treatment of future patients diagnosed with ureteric stones. The results of the study will help plan effective services offered by the NHS. Some patients may report side effects to the study medications but these are usually mild and disappear after a short while. The medications used are not new drugs and have been used in routine use for many years for other health problems.

Where is the study run from?
The study will be conducted in secondary care units across the UK. Co-ordination of the study will occur at the Centre for Healthcare Randomised Trials (CHaRT) in the Health Services Research Unit, University of Aberdeen.

When is the study starting and how long is it expected to run for?
From January 2011 to October 2013.

Who is funding the study?
The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme.

Who is the main contact?
Professor Sam McClinton
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-019469-26

Protocol serial number
HTA 08/71/01

Study information

Scientific Title

Use of drug therapy in the management of symptomatic ureteric stones in hospitalised adults: a multicentre placebo controlled randomised trial of a calcium channel blocker (nifedipine) and an α blocker (tamsulosin)

Acronym
SUSPEND

Study objectives
What is the clinical and cost-effectiveness of the use of an α blocker (tamsulosin) and a calcium channel blocker (nifedipine) in the management of symptomatic urinary stones.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/087101
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/53064/PRO-08-71-01.pdf

On 20/03/2013 the following changes were made to the trial record:
1. The overall trial end date was changed from 30/11/2012 to 31/10/2013.
2. The target number of participants was changed from 2000 to 1200.

On 09/04/2013 the overall trial end date was changed from 31/10/2013 to 01/03/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Fife and Forth Valley Research Ethics Committee, 04/08/2010, ref: 10/S0501/31

Study design
Multicentre double-blind placebo-controlled randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Symptomatic Ureteric Stones

Interventions
Participants will be randomised to one of the following treatment groups.
1. The calcium channel blocker nifedipine, 30 mg once per day
2. The α-blocker tamsulosin, 0.4 mg once per day
3. Placebo once per day

Participants will take one capsule orally per day for a maximum of 28 days and will be followed-up by postal questionnaires sent from the trial office at four and 12 weeks after randomisation.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Nifedipine, tamsulosin

Primary outcome(s)
1. Spontaneous passage of ureteric stones at four weeks (defined as no further intervention required to facilitate stone passage)
2. Incremental cost per quality adjusted life years (QALYs) gained at 12 weeks. QALYs are based on the responses to the EQ-5D.

Key secondary outcome(s))
1. Patient-reported outcomes, at baseline, 4 and 12 weeks:
1.1. Severity of pain as measured by Verbal descriptor scale (VDS) and Numeric Rating scale (NRS)
1.2. Generic health profile as measured by the SF 36 and use of analgesia
2. Clinical outcomes:
2.1. Time to passage of stone
2.2. Further interventions received at 12 weeks
3. Safety: Patient reported discontinuation of trial medications
4. Cost effectiveness:
4.1. NHS primary and secondary care use and costs up to three months, incremental cost per surgical interventions averted
4.2. Modelled incremental cost per QALY beyond the 12 week trial follow-up

Completion date
01/03/2014

Eligibility

Key inclusion criteria
1. Patients presenting acutely with ureteric colic
2. Adults ≥18 ≤ 65 years of age
3. Presence of stone confirmed by non-contrast computed tomography of the kidney, ureter and bladder (CTKUB), or by intravenous urogram (IVU) with subsequent CTKUB confirmation within 12 hours
4. Stone within any segment of the ureter
5. Unilateral ureteric stone
6. Largest stone dimension ≤10 mm
7. Female subjects must be post menopausal (defined as 12 months with no menses without an alternative medical cause), permanently sterilised or willing to use two methods of contraception listed in the protocol prior to the start of dosing until at least 28 days after receiving the last dose of trial medication
8. Capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the consent form

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Women who have a known or suspected pregnancy
2. Women who are breastfeeding
3. Asymptomatic incidentally found ureteric stone
4. Stone not confirmed by CTKUB
5. Stone with any one dimension >10 mm
6. Kidney stone without the presence of ureteric stone
7. Multiple (i.e. ≥ 2) stones within ureter
8. Bilateral ureteric stones
9. Stone in a ureter draining a solitary kidney (either anatomically or functionally)
10. Patients with abnormal renal tract anatomy (such as a duplex system, horseshoe kidney or ileal conduit)
11. Presence of urinary sepsis
12. Chronic renal failure (estinated Glomerular Filtration Rate [eGFR] < 30ml/min)
13. Patients currently taking an α blocker
14. Patients currently taking a calcium channel blocker
15. Patients currently taking PDE5 inhibitors
16. Contraindication or allergy to tamsulosin or nifedipine
17. Patients who are unable to understand or complete trial documentation

Date of first enrolment
01/01/2011

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Grampian
Aberdeen
United Kingdom
AB25 2ZB

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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?
Results article	substudy results	08/07/2015		Yes	No
Results article	results	25/07/2015		Yes	No
Results article	results	01/08/2015		Yes	No
Protocol article	protocol	20/06/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes