SUSPEND SCREENING LOG FORM

Outline data on patients who do not fulfil the inclusion criteria, fulfil the exclusion criteria or who decline participation

Inclusion criteria

- Patient presenting acutely with renal pain (ureteric colic)
- Adult ≥18 to ≤65 years of age
- Presence of stone confirmed by computed tomography of the kidney, ureter and bladder (CTKUB)
- Stone within any segment of the ureter
- Unilateral ureteric stone
- Stone diameter ≤10mm in size
- Female subject is willing to use 2 methods of contraception as advised, or is post menopausal or permanently sterilised
- Capable of giving written informed consent, which includes compliance with the requirements of the trial

Q1 **Date of attempted recruitment** | D | D | / | M | M | / | Y | Y | Y | Y |

Q2 **Year of Birth** | Y | Y | Y | Y |

Q3 **Gender** (please tick) Male ☐ Female ☐

Q4 **Is the patient eligible to participate?** Yes ☐ No ☐

If NO, please give the reason(s) they do not meet the inclusion/exclusion criteria (overleaf)

Please give the reason(s) they do not meet the inclusion/exclusion criteria

- Patient <18 or >65 years of age ☐
- Stone not previously confirmed by CTKUB ☐
- Stone diameter >10mm in size ☐
- Female subject is pregnant or breast-feeding ☐
- Female subject is not willing to comply with contraceptive requirements ☐
- Asymptomatic incidentally found ureteric stones ☐
- Kidney stone without the presence of ureteric stones ☐
- Multiple (i.e ≥2) stones present within ureter ☐
- Bilateral ureteric stones ☐
- Stone is in a ureter draining a solitary kidney (either anatomically or functionally) ☐
- Patient has abnormal renal tract anatomy (such as a duplex system, horseshoe kidney or ileal conduit) ☐
- Presence of urinary sepsis ☐
- Patient has chronic kidney disease stage 4 or stage 5 (eGFR < 30ml/min) ☐
- Patient currently taking an alpha blocker ☐
- Patient currently taking a calcium channel blocker ☐
- Patient currently taking PDE5 inhibitors ☐
- Patient has a contraindication or allergy to tamsulosin or nifedipine ☐
- Participant unable to give informed consent or cannot understand/comply with the requirements of the trial ☐

Q5 Is the patient interested in taking part? YES ☐ NO ☐

If NO, please specify reason (if given)

- No reason given ☐
- Patient not interested in the research study ☐
- Patient does not want to be randomised ☐

Q6 Patient randomised YES ☐ NO ☐

If NO, please specify reason

BASELINE CRF

Participant Study No

SUSPEND

Spontaneous Urinary Stone Passage Enabled by Drugs

BASELINE CASE REPORT FORM (CRF)

CONFIDENTIAL

This study is funded by the NHS National Institute for Health Research
Health Technology Assessment Programme

ISRCTN69423238

Version 1.2, 14 Mar 2012

*PATIENT DETAILS (*Sticker may be used below)

Title ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

First name:	
Surname:	
Address:	
Postcode:	
Mobile telephone number (or other contact number)	
E-mail Address:	
Date of birth:	D D / M M / Y Y Y Y
Gender:	Male ☐ Female ☐
NHS number:	
CHI number (if appropriate):	

CONSULTANT DETAILS

Initials: Surname:

GP DETAILS

Initials: Surname:

Address:

CLINICAL DATA

Date of baseline assessment D D / M M / Y Y Y Y

MEDICAL HISTORY

Duration of current pain due to ureteric stone: _____ Days

History of previous stone disease Yes ☐ No ☐

Current pre-admission analgesic medications Yes ☐ No ☐

If Yes, please select type of medication:

Non-steroidal ☐ Opiate ☐ Other ☐

If Other, please specify _____

Diagnosis of ureteric stone confirmed by:

Test		Date of test
Plain X-ray KUB	☐	D D / M M / Y Y Y Y
IVU	☐	D D / M M / Y Y Y Y
CT KUB	☐	D D / M M / Y Y Y Y

Medications prescribed at this admission.

Analgesics Yes ☐ No ☐

If Yes, please specify: Non-steroidal ☐ Opiates ☐ Other ☐

Antibiotics Yes ☐ No ☐

RANDOMISATION INFORMATION

Telephone Randomisation Service Number: [redacted]

Ureteric stone size (*largest dimension)*: ☐ mm

Stone Location: Upper Ureter ☐ Middle Ureter ☐ Lower Ureter ☐

Participant Study No: ☐☐☐☐☐

Pack ID Number: ☐☐☐☐

Dr <<GP Name>>
<<GP Address 1>>
<<GP Address 2>>
<< GP Address 3>>
<< GP Address 4>>
<< GP Postcode>>

Date

Dear Dr <<Surname>>

Patient name: <<Name>> **Date of birth: <<dob>>**
Patient address: <<address>>

Title of study: Use of drug therapy in the management of symptomatic ureteric stones in hospitalised adults: a multicentre placebo controlled randomised trial of calcium channel blockers (nifedipine) and alpha blockers (tamsulosin)

Your patient has consented to take part in this study which is a multi centre trial funded by the NIHR Health Technology Assessment Programme. The aim of the trial is to provide robust data to guide the treatment of patients with symptomatic ureteric stones. Your patient has been given written information about the trial, including contact details at the hospital and of the central office in Aberdeen.

Your patient has been randomised to take oral capsules containing nifedipine (30 mg) or tamsulosin (0.4 mg) or placebo once daily for a maximum of 28 days. Participants will be followed up in the hospital approximately 4 weeks after commencing treatment for clinical examination. In addition, participants will be sent postal questionnaires from the central co-ordinating office in Aberdeen to complete four and 12 weeks after randomisation.

In the event that your patient suffers a serious adverse event (SAE) that maybe due to the study medication please could you complete the enclosed SAE form and return it to us as soon as possible after you become aware of this. A serious event is defined as one that results in death, hospitalisation, significant/persistent disability/incapacity or is life threatening.

The study is double blinded. Your patient has been given a card to carry with them during the study with a phone number that can be used to unblind them. In the event of an emergency where it is necessary to know what study medication your patient is receiving to make treatment decisions, this phone number should be used.

Female participants have been advised to use two forms of contraception while taking the study drug and for 28 days afterwards. If your patient is female and becomes pregnant in the next two months please report this to the trial office as soon as possible using any of the contact details given.

A more detailed description of the study background is on the back of this letter and we have enclosed information on potential interactions of the study medication for your information. The use of α-blockers, calcium channel blockers, PDE5 inhibitors, rifampacin and digoxin are contraindicated in the trial.

Please do not hesitate to contact us if you have any concerns about your patient being included in this study.

Yours sincerely,

<<Signature>>

<<Name>>, Research Nurse
<<Contact details>>

Mr Sam McClinton, Chief Investigator
[redacted]

GP INFORMATION SHEET

Title of project
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)

Background
Urinary stone disease is very common with an estimated prevalence among the general population of 2-3% and an estimated lifetime risk of 1 in 8 for white males and 5-6% for white females, with males forming stones three times as often as females. Urinary stones often recur and the lifetime recurrence rate is approximately 50%. All urinary tract stones and ureteric stones in particular, have a significant impact on patients' quality of life. They are a common cause of emergency hospital admission due to severe pain with over 15,000 hospital admissions in England annually (HES data 2006-2007) using over 21,500 bed days, resulting in significant calls on health service resources. The pain leads to a requirement for analgesia, time off work and often repeated hospital admissions for therapeutic interventions.

Patients with with smaller sized stones in the lower ureter are traditionally treated expectantly. Those who fail standard supportive care or who subsequently develop complications undergo active treatment such as extra-corporeal shock wave lithotripsy (ESWL), ureteric stenting, ureteroscopy with stone retrieval or in situ lithotripsy, or percutaneous nephrostomy insertion. However, such interventions are expensive, require urological expertise and carry a risk of complications.

In recent years, a growing understanding of ureteric function and pathophysiology has led to the hypothesis that drugs which cause relaxation of ureteric smooth muscle can enhance the spontaneous passage of ureteric stones. This has been termed medical expulsive therapy (MET). Two recent meta-analyses have reported the potential role of α-blockers and calcium channel blockers in MET. In both meta-analyses, the majority of studies involved stones <10 mm located in the lower (distal) ureter. Both reviews concluded that a large, high quality randomised controlled trial is required to confirm their findings; suggesting that MET with either drug class can enhance spontaneous stone passage rate. In addition, several studies have previously reported that MET can significantly reduce the pain burden amongst patients in terms of reducing the frequency of pain episodes, pain severity and analgesic requirements.

In summary, the role of MET in reducing the morbidity and economic costs associated with ureteric stone disease is promising. The majority of clinical trials conducted to date have been small and of poor to moderate quality in terms of trial methodology or design. Furthermore they have lacked a comprehensive economic evaluation. There is thus an urgent need for a definitive randomised controlled trial such as SUSPEND to inform the clinical and cost-effectiveness management of patients with ureteric stone disease.

Brief outline of the study
Ethical and regulatory approvals have been obtained for this trial and written consent has been obtained from participants. Participants may be reviewed in outpatients approximately four weeks after randomisation as per normal clinical practice. Participants are sent postal questionnaires approximately four and 12 weeks after randomisation. The primary clinical outcome of the trial (measured at four weeks) is the spontaneous passage of the stone as measured by the need for further intervention in the treatment of the stone. To reflect the multidimensional nature of the possible effects the intervention may have, there is also a primary health economic outcome of incremental cost per quality adjusted life years (QALYs) gained.

Contraindications, interactions with other medicinal products and other forms of interactions
Taken from the Summary of Product Characteristics (SmPC) for Coracten XL (Nifedipine - last SmPC revision April 2009) and Petyme (Tamsulosin - last SmPC revision 07 August 2013)

Nifedipine is contra-indicated in patients with known hypersensitivity to nifedipine or other dihydropyridines because of the theoretical risk of cross reactivity. It should not be used in clinically

significant aortic stenosis, unstable angina, or during or within one month of a myocardial infarction. It should not be used in patients in cardiogenic shock, for the treatment of acute attacks of angina, or in patients who have had ischaemic pain following its administration previously. The safety of nifedipine capsules in malignant hypertension has not been established.

Nifedipine is contra-indicated in patients with acute porphyria. Nifedipine should not be administered concomitantly with rifampicin since effective plasma levels of nifedipine may not be achieved owing to enzyme induction. As this is a long acting formulation, it should not be administered to patients with hepatic impairment.

Nifedipine may increase the spectrophotometric values of urinary vanillylmandelic acid falsely. However, HPLC measurements are unaffected.

Increased plasma levels of nifedipine have been reported during concomitant use of H_2-receptor antagonists (specifically cimetidine), other calcium channel blockers **(**specifically diltiazem), alcohol, cyclosporin, macrolide antibiotics, gingko biloba and ginseng**.** Azole antifungals may increase serum concentrations of nifedipine. Decreased plasma levels of nifedipine have been reported during concomitant use of antibacterials (specifically rifampicin), and probably also antiepileptics and St John's Wort.

When used in combination with nifedipine, plasma concentrations of quinidine have been shown to be suppressed regardless of quinidine dosage. The plasma concentrations of phenytoin, theophylline, non-depolarising muscle relaxants (e.g. tubocurarine) and possibly digoxin are increased when used in combination with nifedipine. Tacrolimus concentrations may be increased by nifedipine.

Enhanced hypotensive effect of nifedipine may occur with: aldesleukin, alprostadil, anaesthetics, antipsychotics, diuretics, phenothiazides, prazosin and intravenous ionic X-ray contrast medium. Profound hypotension has been reported with nifedipine and intravenous magnesium sulphate in the treatment of pre-eclampsia.

Ritonavir and quinupristin/dalfopristin may result in increased plasma concentrations of nifedipine. Effective plasma levels of nifedipine may not be achieved due to enzyme induction with concurrent administration of erythromycin, carbamazepine and phenobarbitone.

There is an increased risk of excessive hypotension, bradycardia and heart failure with β-blockers.

An increased rate of absorption of nifedipine from sustained release preparation may occur if given concurrently with cisapride. Nifedipine may result in increased levels of mizolastine due to inhibition of cytochrome CYP3A4.

Nifedipine may increase the neuromuscular blocking effects of vecuronium.

Tamsulosin is contraindicated in patients with a hypersensitivity to Tamsulosin, including drug-induced angio-oedema, and those with a history of orthostatic hypotension. Tamsulosin should not be administered to patients with severe hepatic insufficiency.

Concomitant cimetidine brings about a rise in plasma levels of tamsulosin, and furosemide a fall, but as levels remain within the normal range change in dosage is not required. Diclofenac and warfarin may increase the elimination rate of tamsulosin.

There is a theoretical risk of enhanced hypotensive effect when tamsulosin is given concurrently with drugs which may reduce blood pressure, including anaesthetic agents and other α_1-adrenoceptor antagonists.

Tamsulosin should not be given in combination with strong inhibitors of CYP34A in patients with poor metaboliser CYP2D6 phenotype. Tamsulosin should be used with caution in combination with strong and moderate inhibitors of CYP34A.

4 WEEK CRF

Participant Study No

SUSPEND

Spontaneous Urinary Stone Passage Enabled by Drugs

4 WEEK CASE REPORT FORM (CRF)

CONFIDENTIAL

This study is funded by the NHS National Institute for Health Research
Health Technology Assessment Programme

ISRCTN69423238

Version 1.1, 01 Sept 2010

Q1. Did the patient attend the clinic visit?

Yes ☐ No ☐

If Yes, please specify Date of the visit D D / M M / Y Y Y Y

If No, please specify Date of CRF completion D D / M M / Y Y Y Y

Q2. Tests performed at this visit

☐ Plain X-Ray KUB ☐ IVU ☐ CT KUB ☐ None ☐ Other

If other, please give details:

_____

Q3. Has the stone passed?

Yes ☐ No ☐ Don't know ☐

If Yes, when did the patient pass the stone: D D / M M / Y Y Y Y

(If you're not sure please give an approximate date)

Q4. Further Interventions since joined the trial

Has the patient received any other ureteric stone treatment (excluding randomised medication)?

YES ☐ NO ☐

If Yes, please specify date of intervention:

	Yes	DATE OF INTERVENTION
Percutaneous insertion of nephrostomy tube (M13)	☐	D D / M M / Y Y Y Y
Antegrade insertion of stent into ureter (M33)	☐	D D / M M / Y Y Y Y
Therapeutic ureteroscopic operations (includes calculus fragmentation/removal)(M27)	☐	D D / M M / Y Y Y Y
Endoscopic insertion/removal of stent into ureter (M29)	☐	D D / M M / Y Y Y Y
ESWL of calculus of ureter (M31)	☐	D D / M M / Y Y Y Y
Other	☐	D D / M M / Y Y Y Y

If Other treatment, please specify _____

Please provide admission and discharge date(s)

	Date of Admission	Date of Discharge
Admission One	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y
Admission Two	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y

Q5. Further treatment/surgery planned

Is further treatment/surgery planned for persistent ureteric stone? Yes ☐ No ☐

If Yes, please indicate what is intended (*please tick all that are appropriate*):

Percutaneous insertion of nephrostomy tube (M13)	☐	Endoscopic insertion/removal of stent into ureter (M29)	☐
Antegrade insertion of stent into ureter (M33)	☐	ESWL of calculus of ureter (M31)	☐
Therapeutic ureteroscopic operations (includes calculus fragmentation/removal) (M27)	☐	Other	☐

If Other treatment, please specify: _____

12 WEEK CRF

Participant Study No

SUSPEND

Spontaneous Urinary Stone Passage Enabled by Drugs

12 WEEK CASE REPORT FORM (CRF)

CONFIDENTIAL

This study is funded by the NHS National Institute for Health Research Health Technology Assessment Programme

ISRCTN69423238

Version 1.0, 11 May 2010

Please specify date of CRF completion D D / M M / Y Y Y Y

Further Interventions since joined the trial

Has the patient received any other ureteric stone treatment (excluding randomised medication)?

If Yes, please specify date of intervention:

	Yes	DATE OF INTERVENTION
Percutaneous insertion of nephrostomy tube (M13)	☐	D D / M M / Y Y Y Y
Antegrade insertion of stent into ureter (M33)	☐	D D / M M / Y Y Y Y
Therapeutic ureteroscopic operations (includes calculus fragmentation/removal) (M27)	☐	D D / M M / Y Y Y Y
Endoscopic insertion/removal of stent into ureter (M29)	☐	D D / M M / Y Y Y Y
ESWL of calculus of ureter (M31)	☐	D D / M M / Y Y Y Y
Other	☐	D D / M M / Y Y Y Y

If Other treatment, please specify _____

Was admission required for any of the above? **Yes** ☐ **No** ☐

If Yes, please provide admission and discharge date(s)

	Date of Admission	Date of Discharge
Admission One	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y
Admission Two	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y

CHANGE OF STATUS

To be completed on withdrawal/change of status from study

Participant Study Number

Q1 Date of withdrawal D D / M M / Y Y Y Y

Reason for withdrawal

Q2 Participant decided to withdraw? (state reason)

Q3 Any medical reason for withdrawal? (please state reason)

What is participant withdrawing from?

Q4 Follow-up clinic visits?

Yes ☐ No ☐

Q5 Completing questionnaires?

Yes ☐ No ☐

Q6 Relevant outcome data being collected (via hospital and GP records)?

Yes ☐ No ☐

Q7 Contact by telephone from a member of the SUSPEND team?

Yes ☐ No ☐

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Drugs

Serious Adverse Event Form Page 1

Participant Study Number

FOR TRIAL OFFICE USE ONLY

REPORT NO.

DATE REPORTED TO TRIAL OFFICE

D D M M Y Y Y Y

Date of report D D M M Y Y Y Y

Initial Report ☐ Follow Up Report ☐

Is this a possible SUSAR? **Yes** ☐ **No** ☐

Subject Details

Initials ☐☐☐ Date of Birth D D M M Y Y Y Y Gender: Male ☐ Female ☐

Serious Adverse Event

Seriousness criteria (Check all that apply):

Resulted in death ☐ Life-threatening ☐ Hospitalisation/Prolongation of hospitalisation ☐

Persistent/Significant Disability/Incapacity ☐ Congenital anomaly/ Birth defect ☐ Other medically important condition ☐

If Resulted in Death

Date of Death D D M M Y Y Y Y

Cause of Death:

Cause of Death determined by Autopsy Yes ☐ No ☐

Action taken: Drug withdrawn ☐ Dose reduced ☐ Dose increased ☐

Dose not changed ☐ Unknown ☐ Not applicable ☐

Expectedness: Expected ☐ Unexpected ☐ Onset Date: D D M M Y Y Y Y

Diagnosis:

Relationship to Study Drug: None ☐ Possible ☐ Definite ☐

Severity: Mild ☐ Moderate ☐ Severe ☐

Outcome:

Recovered ☐ Recovered with sequelae ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Fatal ☐

Date of Recovery D D M M Y Y

Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU), University of Aberdeen
3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Drugs

Serious Adverse Event Form Page 2

Participant Study Number

Event Narrative	**Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form**

Protocol Treatment(s):

Did the patient take any study medication? Yes ☐ No ☐

Did the subject have to be unblinded? Yes ☐ No ☐

If yes, was subject on placebo? Yes ☐ No ☐

If subject was unblinded and not on placebo please complete below

Study Drug	Dose	Frequency	Start Date (DD/MM/YYYY)	Stop Date (DD/MM/YYYY)	Tick if still ongoing	Route	Batch No

Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU), University of Aberdeen
3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Drugs

Serious Adverse Event Form Page 3

Participant Study Number

Medical History

Provide relevant medical history below or include copy of the Medical History case report form page. Include other illnesses present at time of event, previous study emergent adverse events, and pre-existing medical conditions. If additional space is necessary, use further copies of this page.

☐ Check box if a copy of Medical History page of the case report form is included with this report.

	Condition	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Tick if still ongoing	Medication Required
1					☐ Yes ☐ No
2					☐ Yes ☐ No
3					☐ Yes ☐ No
4					☐ Yes ☐ No
5					☐ Yes ☐ No
6					☐ Yes ☐ No

Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU), University of Aberdeen
3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Drugs

Serious Adverse Event Form Page 4

Participant Study Number

Concomitant Medications

	Medication	Start Date (DD/MM/ YYYY)	End Date (DD/MM/ YYYY)	Tick if ongoing	Dose	Frequency	Route	Indications	Suspect Drug (tick)	Interaction with study drug (tick)
1										
2										
3										
4										
5										
6										

Relevant Tests List only relevant confirmatory test results for event(s), for example from blood tests, diagnostic imaging

	Test	Date (DD/MM/YYYY)	Result	Normal Range-Low	Normal Range-High	Comments
1						
2						
3						

Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU), University of Aberdeen
3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Drugs

Serious Adverse Event Form Page 5

Participant Study Number

Rechallenge Information

1.Did the reaction abate after stopping suspected drug?	Yes		No		N/A
2. Did the reaction reappear after re-introduction of suspect drug?	Yes		No		N/A

Primary Source

Name:	Email address:
Address:	
Telephone number:	Fax number:

Qualification: Physician ☐ Pharmacist ☐ Other Health Professional ☐ Trial Team ☐

To be signed by the Principal Investigator or designee

I am the Principal Investigator Yes ☐ No ☐

If No, Please state designation

I confirm that this is a SAE

Name: (PRINT) _____

Signature: _____

Date: D D M M Y Y Y Y

To be signed by the Chief Investigator or designee in the event of a SUSAR

I am the Chief Investigator Yes ☐ No ☐

If No, Please state designation

I confirm that this is a SUSAR

Name: (PRINT) _____

Signature: _____

Date: D D M M Y Y Y Y

Reported ☐

Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU), University of Aberdeen
3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

GP Serious Adverse Event Form Page 1

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Dru

FOR TRIAL OFFICE USE ONLY

REPORT NO.	DATE REPORTED TO TRIAL OFFICE
	D D M M Y Y Y Y

Subject Details

Initials | | | | Date of Birth D D M M Y Y Y Y Gender Male ☐ Female ☐

Subject I.D./Randomisation No | | | | | |

Serious Adverse Event

Seriousness criteria (Check all that apply):

Resulted in death ☐ Life-threatening ☐ Hospitalisation/Prolongation of hospitalisation ☐

Persistent/Significant Disability/Incapacity ☐ Congenital anomaly/ Birth defect ☐ Other medically important condition ☐

Diagnosis:

Relationship to Study Drug: None ☐ Possible ☐ Definite ☐

Action taken: Drug withdrawn ☐ Unknown ☐ Not applicable ☐

If Resulted in Death

Date of Death	Cause of Death:	Cause of Death determined by Autopsy:
D D M M Y Y Y Y		Yes ☐ No ☐

Protocol Treatment(s):

Did the patient take any study medication?	Yes ☐	No ☐	Unknown ☐
Did the subject have to be unblinded?	Yes ☐	No ☐	Unknown ☐
If yes, was subject on placebo?	Yes ☐	No ☐	Unknown ☐

Event Narrative **Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form**

The SUSPEND trial, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU),
University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

GP Serious Adverse Event Form Page 2

Details of Person Reporting	
Name	Email
Address	**Telephone**
Country	Fax
Qualification GP ☐ Other Health Professional ☐ Other ☐ Please state _____	

The SUSPEND trial, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU),
University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Dr

FOR TRIAL OFFICE USE ONLY

R&D reference | | | | | | | | | | |

Centre ID | | | |

Eudract No. | | | | | | | | | | |

Subject ID | | | | | | | | |

Subject initials | | |

DO NOT SEND IDENTIFIABLE DATA OR SOURCE DOCUMENTS WITH THIS REPORT

1. MATERNAL INFORMATION

Date of Birth

D	D	M	M	Y	Y	Y	Y

Date of last menstrual period

D	D	M	M	Y	Y	Y	Y

Expected date of delivery

D	D	M	M	Y	Y	Y	Y

Methods of contraception _____

Contraception used as instructed

Yes ☐ **No** ☐ **Uncertain** ☐

2. MEDICAL HISTORY (include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy. If none mark N/A)

3. PREVIOUS OBSTETRIC HISTORY

	Gestation week	Outcome including any abnormalities
1		
2		
3		
4		
5		

The SUSPEND Trial, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU),
University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

FOR TRIAL OFFICE USE ONLY

R&D reference | | | | | | | | | | |

Centre ID | | |

Eudract No. | | | | | | | | | | |

Subject ID | | | | | | | | |

Subject initials | | |

4. DRUG INFORMATION (list all therapies taken prior to and during pregnancy)

Name of drug	Daily dose	Route	Date Started	Date Stopped	Treatment Start (week of pregnancy)	Treatment Stop (week of pregnancy)
			D D M M Y Y	D D M M Y Y	D D	D D
			D D M M Y Y	D D M M Y Y	D D	D D
			D D M M Y Y	D D M M Y Y	D D	D D

5. PRENATAL INFORMATION

Have any specific tests e.g. amniocemtesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far? **Yes** ☐ **No** ☐ **Uncertain** ☐

If yes please specify test date and results

	Test	Date	Result
1		D D M M Y Y	
2		D D M M Y Y	
3		D D M M Y Y	

The SUSPEND Trial, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU),
University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Dru

FOR TRIAL OFFICE USE ONLY

R&D reference | | | | | | | | | | |

Centre ID | | | |

Eudract No. | | | | | | | | | | |

Subject ID | | | | | | | | |

Subject initials | | |

6. PREGNANCY OUTCOME

(a) Abortion **Yes** ☐ **No** ☐

If yes

Therapeutic ☐ Planned ☐ Spontaneous ☐

Please specify the reason and any abnormalities (if known):

(b) Delivery **Yes** ☐ **No** ☐

If yes

Normal ☐ Forceps/Ventouse ☐ Caesarean ☐

Maternal complications or problems related to birth:

Date of abortion D D M M Y Y Y Y

Delivery date D D M M Y Y Y Y

7. MATERNAL PREGNANCY ASSOCIATED EVENTS

If the mother experiences an SAE during the pregnancy, please indicate here and complete and SAE form and submit it to the Trial Office immediately.

8. CHILD OUTCOME

Normal ☐ Abnormal ☐ Stillbirth ☐

If any abnormalities please specify and provide dates

Sex	**Male** ☐	**Female** ☐	**Agpar Scores:**
Height	**cm**		**1 min**
Weight	**kg**		**5 mins**
Head circumference	**cm**		**10 mins**

The SUSPEND Trial, Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit (HSRU),
University of Aberdeen, 3rd Floor, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD
Tel: [redacted], Fax: [redacted], Email: [redacted]

SUSPEND
Spontaneous Urinary Stone Passage Enabled by Dru

FOR TRIAL OFFICE USE ONLY
R&D reference | Centre ID
Eudract No. | Subject ID | Subject initials

9. ASSESSMENT OF SERIOUSNESS (OF PREGNANCY OUTCOME)

Non serious ☐ Involved prolonged inpatient hospitalisation ☐ Results in persistent or significant disability/incapacity ☐
Life Threatening ☐ Congenital anomaly/birth defect ☐ Other significant medical events ☐

Mother died ☐ Date of death D D M M Y Y Y Y
Stillbirth/neonate died ☐ Date of death D D M M Y Y Y Y

10. ASSESSMENT OF CAUSALITY (OF PREGNANCY OUTCOME)

Please indicate the relationship between pregnancy outcome
Unrelated ☐ Possibly* ☐ Probably* ☐ Definitely* ☐
If any of the fields marked* have been checked, the outcome is considered RELATED to the study drug.

11. ADDITIONAL INFORMATION

12. INFORMATION SOURCE

Name _____
Position _____
Address _____
Signature _____
Date of Report D D M M Y Y Y Y

To be signed by the Chief Investigator

SUSAR
I confirm that this is a SUSAR ☐
Name (PRINT) _____

Signature _____ Date D D M M Y Y
Reported ☐

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