

Center # 1 = GWU 4 = UAB
 2 = TJU 5 = UPMC-Mercy
 3 = UPMC

**THE STONE STUDY
 SCREENING LOG**

Form ST01 v.1
 September 8, 2014
 Page _____

Complete this form for all patients presenting to the Emergency Department with possible kidney stone diagnosis.

Screening Number SCREEN	Patient Identifier (not keyed)	1. Date screened (mm/dd/yyyy) LSCRDT	2. Previous screen? LPRVSCR	2a. If YES, Previous Screening Number LPRVSCRN	3. Gender LGEM	4. Race LRACE	5. Ethnicity LETHNIC	6. Screen status LSTAT US	6a. If screen status=2, Reason LINELIG	6a.1) If reason code = 99 "Other", explain LOTHREAS	6b. If screen status= 3, STONE patient # LPATID	7. Initials of person completing form LINITIS
		//_	Y N									
		//_	Y N									
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GENDER
 1 = Female
 2 = Male

ETHNICITY
 0 = No, Not Hispanic / Latino
 1 = Yes, Hispanic / Latino

RACE
 1 = American Indian / Alaskan Native
 2 = Asian
 3 = Native Hawaiian / Pacific Islander
 4 = Black / African American
 5 = White
 6 = Unknown or Not Reported

SCREEN STATUS CODES
 1 = Patient declined consent
 2 = Ineligible
 3 = Randomized

REASONS FOR INELIGIBILITY

01 = Age < 18	09 = Prior renal transplant or donation	17 = Stone expulsion in the ED
02 = No evidence of ureterolithiasis	10 = History of renal insufficiency	18 = Largest stone diameter ≥ 9mm
03 = No phone	11 = Fever	19 = Admitted to the hospital
04 = Concurrent UTI	12 = History of hypersensitivity to tamsulosin	20 = Prisoner or ward of state
05 = Prior kidney/ureter surgery	13 = Taking α-blockers or Ca ⁺⁺ blockers	21 = Breastfeeding mother
06 = Pregnant	14 = Taking vardenafil	22 = Prior enrollment
07 = Anatomical GU abnormality	15 = Floppy iris syndrome	23 = Bladder stone
08 = Ipsilateral/solitary kidney	16 = Cataract surgery within 60 days	24 = Taking steroids
		25 = Non-English speaker
		99 = Other

**THE STONE STUDY
CLINICAL SCREENING FORM**

Form ST02 v.2
December 23, 2014
Page 1 of 2

STONE ID:

1.	Screening Number:	SSCREEN	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2.	Date of screening (mm/dd/yyyy)	SDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3.	Initials of person completing this form	SINITS	<input type="text"/> <input type="text"/> <input type="text"/>

A. Demographics and Social Characteristics

4.	Age (not eligible if < 18 years)	SAGE	<input type="text"/> <input type="text"/> years
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B. Current Medications

5.	Known allergy to tamsulosin?	SALLTAM	Y N
6.	Currently taking calcium channel blockers?	SALPHAB	Y N
7.	Currently taking steroids?	SSTEROID	Y N
8.	Currently taking vardenafil?	SLEVITRA	Y N

If allergic to tamsulosin OR on calcium channel blockers, steroids or vardenafil, patient is ineligible.

9.	Currently taking other medication on a regular basis?	SMEDS	Y N
a. If YES , list current medications (name only)			
<input type="text"/>		<input type="text"/>	
<input type="text"/>		<input type="text"/>	

C. Current Symptoms

10.	Symptoms	Circle all that apply	
	a. Increased need to urinate	SURIN	Y N
	b. Urinating more often at night	SURNIGHT	Y N
	c. Pain when urinating	SPAINUR	Y N
	d. Feeling of not emptying bladder completely	SNOTEMP	Y N
	e. Nausea	SNAUSEA	Y N
	f. Vomiting	SVOMIT	Y N
	g. Dizziness	SDIZZY	Y N
	h. Chest pain	SCHPAIN	Y N
	i. Fever	SFEVER	Y N
	j. Side/flank pain	SSIDEP	<input type="checkbox"/> 0 = None 1 = Left 2 = Right 3 = Bilateral
	k. Lower abdomen pain	SLOWABDP	<input type="checkbox"/> 0 = None 1 = Left 2 = Right 3 = Bilateral
	l. Scrotum or groin pain	SGROINP	<input type="checkbox"/> 0 = None 1 = Left 2 = Right 3 = Bilateral

**THE STONE STUDY
CLINICAL SCREENING FORM**

Form ST02
December 23, 2014
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STONE ID:

D. Medical History (by report)

11.	Past history of kidney stones?	SHXKSTN	Y N
	If YES, a. How many episodes? <input type="text"/> <input type="text"/> SNUMSTN b. Date of most recent episode <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> SMONSTN / SYRSTN		
12.	Family history of kidney stones (parents/siblings)?	SFAMHX	Y N

E. Initial Vital Signs (at triage)

13.	Blood pressure	SIBPSYS/ SIBPIA	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> mmHg
14.	Heart rate	SIHR	<input type="text"/> <input type="text"/> <input type="text"/> bpm
15.	Temperature (not eligible if temp>101.5 °F)	SITEMP	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> °F

F. Urine Analysis Results

16.	Dipstick:		
	a. Glucose (mg/ul)	SDIPGLUC	<input type="checkbox"/> 0 = Normal 3 = 250 <input type="checkbox"/> 1 = 50 4 = 500 <input type="checkbox"/> 2 = 100 5 = 1000
	b. Blood (erythrocytes/ul)	SDIPBLD	<input type="checkbox"/> 0 = Negative 2 = Abt 50 <input type="checkbox"/> 1 = Trace 3 = Abt 250
	c. White cells (leukocytes)	SDIPWBC	<input type="checkbox"/> 0 = Negative 2 = + <input type="checkbox"/> 1 = Trace 3 = ++
17.	Was an HCG done? (necessary for all women of child-bearing age)	SHCG	Y N N/A
	a. If YES, Results positive? (Not eligible for study if positive)	SHCGRES	Y N
18.	Urinalysis microscopy done?	SMICRO	Y N
	If YES,	Use scale for questions a – c	
	a. Blood	SMICBLD	<input type="checkbox"/> 0 = 0,none,negative,WNL <input type="checkbox"/> 1 = 1-5,trace,rare,present, slight <input type="checkbox"/> 2 = 6-15,moderate <input type="checkbox"/> 3 = 16-30,many,frequent <input type="checkbox"/> 4 = > 30,innumerable,TNTC
	b. White cells	SMICWBC	
	c. Bacteria	SMICBACT	

G. Discharge from ED

19.	Stone expelled in the ED? (Not eligible if expelled)	SEXPEL	Y N
20.	Final primary ED diagnosis:	SFINDX	<input type="checkbox"/> 1 = Renal colic <input type="checkbox"/> 2 = Stone <input type="checkbox"/> 3 = Other
21.	Patient admitted? (Not eligible if admitted)	SADMIT	Y N
	a. If YES, to which service?	SADMSERV	<input type="checkbox"/> 1 = Urology <input type="checkbox"/> 2 = Surgery <input type="checkbox"/> 3 = Medicine <input type="checkbox"/> 4 = Other

THE STONE STUDY
RADIOLOGICAL SCREENING FORM

Form ST03 v.1
 September 8, 2014
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STONE ID: PATID

1.	Date of screening (mm/dd/yyyy)	RDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2.	Initials of person completing this form	RINITS	<input type="text"/> <input type="text"/> <input type="text"/>
3.	CT result	RCTSTONE	<input type="checkbox"/> 0 = No stones 1 = Single stone 2 = Multiple stones 3 = Bladder stone(s)

No stones (0) or bladder stones (3), patient is ineligible to be randomized. SKIP to question 13.

4.	Side of symptomatic stone	RSIDESYM	<input type="checkbox"/> 1 = Left 2 = Right
5.	Location of symptomatic stone	RLOCASYM	<input type="checkbox"/> 1 = Renal pelvis 2 = Proximal ureter 3 = Mid ureter 4 = Distal ureter 5 = UVJ
6.	Diameter of symptomatic stone	RSIZESYM	<input type="text"/> <input type="text"/> . <input type="text"/> mm
7.	Hydronephrosis?	RHYDRON	Y N
8.	Stranding?	RSTRAND	Y N

If Question 3 = Single stone (1), SKIP to Question 13.
If Question 3 = Multiple stones (2), CONTINUE.

9.	Number of stones	RNUMSTN	<input type="text"/> <input type="text"/>
10.	Side of additional stone(s)	RSIDELOC	<input type="checkbox"/> 1 = Left 2 = Right 3 = Bilateral
11.	Location of additional stone(s)		(more than one may apply)
	a. Renal pelvis	RLRENPEL	Y N
	b. Proximal ureter	RLPROXUR	Y N
	c. Mid ureter	RLMIDUR	Y N
	d. Distal ureter	RLDISTUR	Y N
	e. UVJ	RLUVJ	Y N
	f. Kidney	RLKIDNEY	Y N
12.	Is the symptomatic stone the largest stone?	RLARGEST	Y N
	If NO,		
	a. Diameter of largest stone	RDIALAR	<input type="text"/> <input type="text"/> . <input type="text"/> mm
13.	Initials of radiologist reading images	RINITSRAD	<input type="text"/> <input type="text"/> <input type="text"/>

PATID

**THE STONE STUDY
FOLLOW- UP FORM**

Form ST10 v.1
September 1, 2015
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STONE ID:

1.	Post ED day:	FDAY	<input type="text"/> <input type="text"/> <input type="text"/>
ED visit is day 0 and scheduled follow up calls are on days 2, 7, 15, 20, 29 and 90. All questions should be answered for the time since the last contact unless otherwise specified.			
2.	Date of contact	FDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3.	Initials of person completing this form	FINITS	<input type="text"/> <input type="text"/> <input type="text"/>
4.	Patient reached?	FREACH	Y N
If YES, continue, If NO, STOP. If Day 90 contact, SKIP to question 12.			
5.	Have you taken the study medication since the last contact?	FSTDYMED	Y N
	If YES, a. How many doses since the last contact?	FSMEDDOS	<input type="text"/> <input type="text"/>
6.	Have you taken any open-label tamsulosin/Flomax since the last contact?	FOPENLAB	Y N
	If YES, a. How many doses since the last contact?	FOLDOS	<input type="text"/> <input type="text"/>
7.	Are you currently taking an NSAID?	FNSAID	Y N
	If YES, a. Dose?	FNSDOS	<input type="text"/> 1 = 200mg 4 = 800mg 2 = 400mg 5 = Other 3 = 600mg
	b. How many pills since the last contact?	FNSNUM	<input type="text"/> <input type="text"/>
8.	Are you currently taking Percocet?	FPERC	Y N
	If YES, a. Dose per day?	FPERCDOS	<input type="text"/> 1 = 1 tablet 2 = 2 tablets 3 = 3 tablets 4 = Other
9.	Are you currently taking any other analgesic?	FANALG	Y N
	If YES, a. Type of analgesic?	FANALGT	<input type="text"/> 1 = Acetaminophen 2 = Demerol 3 = Other
	If Other (3), 1) Specify:	<input type="text"/>	
	b. Dose?	FANDOS	<input type="text"/> <input type="text"/> <input type="text"/> mg
	c. How many pills have you taken since last contact?	FANNUM	<input type="text"/> <input type="text"/>
10.	Have you taken a steroid medication since the last contact?	FSTEROID	Y N
11.	Have you taken a contraindicated medication since the last contact?	FCONTRA	Y N

PATID

**THE STONE STUDY
FOLLOW- UP FORM**

Form ST10 v.1
September 1, 2015
Page 2 of 3

STONE ID:

Post ED Day: _____

12.	Are you employed?	FEMPLOYD	Y N
	If YES,		
	a. Have you returned to work?	FRETWORK	Y N
13.	Side effects: Have you experienced.....		
	a. dizziness at rest?	FDIZRST	Y N
	b. dizziness when standing up?	FDIZSND	Y N
	c. abnormalities of ejaculation?	FABNEJAC	Y N female
	d. stomach upset, nausea or vomiting (GI disorder)?	FGASTRO	Y N
	e. bloody/black stool, or bloody vomiting (GI bleeding)?	FGBLEED	Y N
	f. abdominal pain or a stomach ulcer?	FULCER	Y N
	g. urinary tract infection(s)?	FUTI	Y N
	h. facial flushing?	FFACFLSH	Y N
	i. headache(s)?	FHEADACH	Y N
	j. tachycardia or fast heart rate?	FTACHY	Y N
14.	Have you had a follow-up visit with any doctor for the stone ?	FFUPVST	Y N
	If YES, Name and phone of MD	_____	
	a. Date of visit:	FFUPDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	b. Specialty:	FFUPSPEC	<input type="text"/> <ul style="list-style-type: none"> 1 = PCP 2 = Urologist 3 = Nephrologist 4 = Other
	If Other (4),	_____	
	1) Specify:	<input type="text"/>	
15.	Have you returned to the ER for the stone(s)?	FRETER	Y N
	If YES,		
	a. How many visits?	FERNUMV	<input type="text"/> <input type="text"/>
	b. Date of most recent visit?	FERDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	ER: _____		
	c. CT performed?	FERCT	Y N
	d. Ultrasound performed?	FERNUS	Y N

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**THE STONE STUDY
FOLLOW- UP FORM**

Form ST10 v.1
September 1, 2015
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STONE ID:

Post ED Day: _____

16.	Have you been hospitalized because of the stone(s)? FHOSP	Y N
	If YES, a. How many hospitalizations? FHSPNUM	<input type="text"/> <input type="text"/>
	b. Date of most recent hospitalization? FHSPDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Hospital? _____	
	c. How many nights did you spend in the hospital? FHSPNITE	<input type="text"/> <input type="text"/> nights
	d. CT performed? FHSPCT	Y N
	e. Ultrasound performed? FHSPUS	Y N
17.	Have you expelled a stone? FEXPEL	<input type="text"/> 0 = No 1 = Seen 2 = Captured
	If Seen (1) or Captured (2), a. Date: FEXPDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
18.	Have you expelled multiple stones? FEXPMULT	Y N
	If YES, a. How many stones? FMULTNUM	<input type="text"/> <input type="text"/>
19.	Have you had or been scheduled for surgical intervention for stone? FSURG	<input type="text"/> 0 = No 1 = Yes, scheduled 2 = Yes, already done
	If YES, scheduled (1) or performed (2): a. Type of procedure: FSURGTYP	<input type="text"/> 1 = Lithotripsy 2 = Ureteral stent 3 = Ureteroscopy 4 = Laser Blast 5 = Other
	b. Date: FSRGDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
20.	Have you experienced any adverse events not mentioned above? FAE	Y N

Please complete the Adverse Event Form (ST12) for any adverse experience reported by the participant that is serious or NOT captured on this form. Adverse events may include, but are not limited to: drug reaction, side effect (not listed above), abnormal laboratory value, hospitalization, other complication or pre-existing condition that worsened.

Please contact the Coordinating Center with any questions.

THE STONE STUDY
RADIOLOGICAL FOLLOW-UP FORM

Form ST11 v.1
November 19, 2014
Page 1 of 1

STONE ID Number:

1.	Follow-up CT performed?	DCTPERF	Y N
	If NO,		
	a. Reason:	DNOCTRSN	<input type="checkbox"/> <ul style="list-style-type: none"> 1 = Refused 2 = Captured/seen stone 3 = CT or scan already done 4 = Urologist recommendation 5 = Radiation exposure 6 = Surgical intervention 9 = Other
If study CT performed, CONTINUE.			
If no study CT performed, STOP.			
2.	Date of scan (mm/dd/yyyy):	DDATE	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3.	Initials of person completing this form:	DINITS	<input type="text"/> <input type="text"/> <input type="text"/>
4.	Performed follow-up CT for study?	DDAY28CT	Y N
5.	CT result:	DCTSTONE	<input type="checkbox"/> <ul style="list-style-type: none"> 0 = No stones 1 = Single stone 2 = Multiple stones
If there are no stones (0), SKIP to question 10.			
6.	Number of stones:	DNUMSTN	<input type="text"/> <input type="text"/>
7.	Side of stone(s):	DSIDESTN	<input type="checkbox"/> <ul style="list-style-type: none"> 1 = Left 2 = Right 3 = Bilateral
8.	Location of additional stone(s):		(more than one may apply)
	a. Renal pelvis	DLRENPEL	Y N
	b. Proximal ureter	DLPROXUR	Y N
	c. Mid ureter	DLMIDUR	Y N
	d. Distal ureter	DLDISTUR	Y N
	e. UVJ	DLUVJ	Y N
	f. Kidney	DKIDNEY	Y N
9.	Diameter of largest stone:	DSIZELG	<input type="text"/> <input type="text"/> . <input type="text"/> mm
10.	Hydronephrosis?	DHYDRON	Y N
11.	Stranding?	DSTRAND	Y N
12.	Initials of radiologist reading images:	DRDINITS	<input type="text"/> <input type="text"/> <input type="text"/>