

Summarized variables in SCREENING (excluding open-text)

NAME	LABEL
StudyEvent	StudyEvent
EDEvalGCS	ED Evaluation GCS
Inclusion1	Is patient less than 18 years of age?
Inclusion2	Does patient have a diagnosis of DKA?
Inclusion3	Is patient's serum glucose or finger stick glucose concentration > 300 mg/dL?
Inclusion4	Is patient's venous pH < 7.25 or serum bicarbonate concentration < 15 mmol/L?
Exclusion1	Does patient have a pre-existing neurological disease that substantially impacts mental status or neurocognitive exam?
Exclusion2	Does patient present with concomitant alcohol or drug use, head trauma, meningitis or other conditions which might affect neurological function?
Exclusion3	Has patient been transferred after initiation of DKA treatment more than one 10 mL/kg intravenous bolus?
Exclusion4	Is patient known to be pregnant?
Exclusion5	Has patient been enrolled in this study twice previously?
Exclusion6	Has patient been receiving IV fluids at a maintenance rate or greater for more than two hours?
Exclusion7	Has it been more than four hours since patient started DKA therapy?
Exclusion9	Has the patient been given hyperosmolar therapy (i.e. mannitol or 3% normal saline) prior to or since arriving at your site?
Exclusion10	Does the treating physician intend to immediately administer hyperosmolar therapy (i.e. mannitol or 3% normal saline) to the patient?
Exclusion11	Is the patient's baseline GCS 11 or less?
Eligible	Eligible
Approached	Approached for Permission
Permission	Permission Given
Recheck1	Was informed consent obtained within 2 hours of IV fluid initiation?
Recheck2	Was informed consent obtained within 4 hours of DKA treatment initiation?
Randomized	Randomized
RxGroup	Treatment Arm
PrevEnrolled	Previously Enrolled
PERMISSIONDAY	Permission Day (relative to randomization)
RANDDAY	Randomization Day (relative to randomization)
SCREENDAY	Screening Day (relative to randomization)

Variables in SCREENING without summary

NAME	LABEL
PUDID	Subject ID
Occurrence	Occurrence
ItemGroupRepeatKey	ItemGroupRepeatKey
ScreenTime	Screening Time
PermissionTime	Permission Time
RandTime	Randomization Time
PrevSubjectID	Subject ID

SCREENING Summaries

	N	Percent
StudyEvent		
Screening	1389	100%
Is patient less than 18 years of age?		
Yes	1389	100%
Does patient have a diagnosis of DKA?		
Yes	1389	100%
Is patient's serum glucose or finger stick glucose concentration > 300 mg/dL?		
Yes	1389	100%
Is patient's venous pH < 7.25 or serum bicarbonate concentration < 15 mmol/L?		
Yes	1389	100%
Does patient have a pre-existing neurological disease that substantially impacts mental status or neurocognitive exam?		
No	1389	100%
Does patient present with concomitant alcohol or drug use, head trauma, meningitis or other conditions which might affect neurological function?		
No	1389	100%
Has patient been transferred after initiation of DKA treatment more than one 10 mL/kg intravenous bolus?		
No	1389	100%
Is patient known to be pregnant?		
No	1389	100%
Has patient been enrolled in this study twice previously?		
No	1389	100%
Has patient been receiving IV fluids at a maintenance rate or greater for more than two hours?		
No	1389	100%
Has it been more than four hours since patient started DKA therapy?		
No	1389	100%
Has the patient been given hyperosmolar therapy (i.e. mannitol or 3% normal saline) prior to or since arriving at your site?		
.	589	42%
No	800	58%
Does the treating physician intend to immediately administer hyperosmolar therapy (i.e. mannitol or 3% normal saline) to the patient?		
.	589	42%
No	800	58%
Is the patient's baseline GCS 11 or less?		
.	589	42%
No	800	58%

(Continued)

SCREENING Summaries

	N	Percent
Eligible		
Yes	1389	100%
Approached for Permission		
Yes	1389	100%
Permission Given		
Yes	1389	100%
Was informed consent obtained within 2 hours of IV fluid initiation?		
Yes	1389	100%
Was informed consent obtained within 4 hours of DKA treatment initiation?		
Yes	1389	100%
Randomized		
Yes	1389	100%
Treatment Arm		
A1:Additional bolus of 10 ml/kg; 0.45% NS for assumed 10% body weight deficit	344	25%
A2:Additional bolus of 10 ml/kg; 0.9% NS for assumed 10% body weight deficit	351	25%
B1:No additional bolus; 0.45% NS for assumed 5% body weight deficit	345	25%
B2:No additional bolus; 0.9% NS for assumed 5% body weight deficit	349	25%
Previously Enrolled		
No	1255	90%
Yes	134	10%

SCREENING Summaries

	N	Min	Max	Mean	SD	Q1	Med	Q3
ED Evaluation GCS	1,389	6	15	15	1	15	15	15
Permission Day (relative to randomization)	1,389	-1	0	-0	0	0	0	0
Randomization Day (relative to randomization)	1,389	0	0	0	0	0	0	0
Screening Day (relative to randomization)	1,389	-1	0	-0	0	0	0	0