

Summarized variables in INELIGIBILITY (excluding open-text)

NAME	LABEL
StudyEvent	StudyEvent
IneligibleInclusion1	Is patient less than 18 years of age?
IneligibleInclusion2	Does patient have a diagnosis of DKA?
IneligibleInclusion3	Is patient's serum glucose or finger stick glucose concentration > 300 mg/dL?
IneligibleInclusion4	Is patient's venous pH < 7.25 or serum bicarbonate concentration < 15 mmol/L?
IneligibleExclusion1	Does patient have a pre-existing neurological disease that substantially impacts mental status or neurocognitive exam?
IneligibleExclusion2	Does patient present with concomitant alcohol or drug use, head trauma, meningitis or other conditions which might affect neurological function?
IneligibleExclusion3	Has patient been transferred after initiation of DKA treatment more than one 10 mL/kg intravenous bolus?
IneligibleExclusion4	Is patient known to be pregnant?
IneligibleExclusion5	Has patient been enrolled in this study twice previously?
IneligibleExclusion6	Has patient been receiving IV fluids at a maintenance rate or greater for more than two hours prior to arrival at the study center hospital?
IneligibleExclusion7	Has it been more than four hours since patient started DKA therapy prior to arrival at the study center hospital?
IneligibleExclusion9	Has the patient been given hyperosmolar therapy (i.e. mannitol or 3% normal saline) prior to or since arriving at your site?
IneligibleExclusion10	Does the treating physician intend to immediately administer hyperosmolar therapy (i.e. mannitol or 3% normal saline) to the patient?
IneligibleExclusion11	Is the patient's baseline GCS 11 or less?
INELIGIBLEDAY	Day ineligibility discovered (relative to randomization)

Variables in INELIGIBILITY without summary

NAME	LABEL
PUDID	Subject ID
Occurrence	Occurrence
ItemGroupRepeatKey	ItemGroupRepeatKey

INELIGIBILITY Summaries

	N	Percent
StudyEvent		
Unscheduled	9	100%
Is patient less than 18 years of age?		
Yes	9	100%
Does patient have a diagnosis of DKA?		
No	2	22%
Yes	7	78%
Is patient's serum glucose or finger stick glucose concentration > 300 mg/dL?		
No	1	11%
Yes	8	89%
Is patient's venous pH < 7.25 or serum bicarbonate concentration < 15 mmol/L?		
No	1	11%
Yes	8	89%
Does patient have a pre-existing neurological disease that substantially impacts mental status or neurocognitive exam?		
No	9	100%
Does patient present with concomitant alcohol or drug use, head trauma, meningitis or other conditions which might affect neurological function?		
No	9	100%
Has patient been transferred after initiation of DKA treatment more than one 10 mL/kg intravenous bolus?		
No	6	67%
Yes	3	33%
Is patient known to be pregnant?		
No	9	100%
Has patient been enrolled in this study twice previously?		
No	8	89%
Yes	1	11%
Has patient been receiving IV fluids at a maintenance rate or greater for more than two hours prior to arrival at the study center hospital?		
No	8	89%
Yes	1	11%
Has it been more than four hours since patient started DKA therapy prior to arrival at the study center hospital?		
No	9	100%
Has the patient been given hyperosmolar therapy (i.e. mannitol or 3% normal saline) prior to or since arriving at your site?		
No	9	100%

(Continued)

INELIGIBILITY Summaries

	N	Percent
Does the treating physician intend to immediately administer hyperosmolar therapy (i.e. mannitol or 3% normal saline) to the patient?		
No	9	100%
Is the patient's baseline GCS 11 or less?		
No	9	100%

INELIGIBILITY Summaries

	N	Min	Max	Mean	SD	Q1	Med	Q3
Day ineligibility discovered (relative to randomization)	9	0	1,319	155	437	0	0	6