

A LARGE RANDOMISED PLACEBO CONTROLLED TRIAL AMONG TRAUMA PATIENTS WITH OR AT RISK OF SIGNIFICANT HAEMORRHAGE, OF THE EFFECTS OF ANTIFIBRINOLYTIC TREATMENT ON DEATH AND TRANSFUSION REQUIREMENT

DATA DICTIONARY FOR THE DATA SET CRASH-2 DATA FOR SUNGAI BULOH

EXCLUDED FROM THE CRASH-2 DATA IS THE VARIABLE: TREATMENT CODE

Variable	Label	Comments	Maximum Length	Туре	Codes
ientryid	Unique number assigned by the database to each entry form on entry into the database		5	Integer	Range 1 to 20270
isource	Method by which the entry form was sent to the trial coordinating centre		1	Integer	1 = Telephone randomisation via Clinical Trials Service Unit (CTSU) 2 = Telephone randomisation via Clinical Trials Service Unit entered manually by CTSU 3 = electronic CRF sent via email 4 = paper CRF entered onto electronic CRF by Trial Coordinating Centre 5 = electronic CRF uploaded onto Crashnet (Trial) server
trandomised	Date and time of randomisation of the patient	Date and time stamp entered automatically by computer upon randomisation at Clinical Trials Service Unit	8	Date and time	Format DD/MM/YYYY HH:MM:SS
ioutcomeid	Unique number assigned by the database to each outcome form on entry into the database		5	Integer	Range 1 to 20199
isex	Sex of the patient	Patient Entry Q.4 Patient sex	1	Integer	1 = Male 2 = Female NULL (blank) = missing data

Variable	Label	Comments	Max Length	Туре	Codes
iage	Estimated age of the patient	Patient Entry	2	Integer	Range 1 to 99
	if date of birth not known	Q7b NO –			NULL (blank) = missing data
		approximate age			
ninjurytime	Number of hours since	Patient Entry	2	Number	Range 0.1 to 96
	injury	Q.8 Estimated			0 and 999 = missing data
		number of hours			
		since injury			
iinjurytype	Type of injury	Patient Entry	1	Integer	1 = Blunt
		Q.9 Type of injury			2 = Penetrating
					3 = Blunt and penetrating
isbp	Systolic blood pressure in	Patient Entry	3	Integer	Range 4 to 250
	mmHg	Q.10 Systolic BP			NULL (blank), 0 and 999 = missing data
irr	Respiratory rate per minute	Patient Entry	2	Integer	Range 1 to 96
		Q.11 Respiratory rate			NULL (blank) and 0 = missing data
icc	Central capillary refill time	Patient Entry	2	Integer	Range 1 to 60
	in seconds	Q.12 Central capillary refill time			NULL (blank) = missing data
ihr	Heart rate per minute	Patient Entry	3	Integer	Range 3 to 220
	· ·	Q.13 Heart rate			NULL (blank) = missing data
igcseye	Glasgow Coma Score eye	Patient Entry	1	Integer	Range 1 to 4
	opening	Q.14 Eye opening			NULL (blank) = missing data
igcsmotor	Glasgow Coma Score motor	Patient Entry	1	Integer	Range 1 to 6
	response	Q.14 Motor response			NULL (blank) = missing data
igcsverbal	Glasgow Coma Score verbal	Patient Entry	1	Integer	Range 1 to 5
	response	Q14. Verbal response			NULL (blank) = missing data
igcs	Glasgow Coma Score total	Patient Entry	2	Integer	Range 3 to 15
	score	Q14. Glasgow Coma			NULL (blank) = missing data
		Score			

Variable	Label	Comments	Max Length	Туре	Codes
ddeath	Date of death	Outcome Form Q.3.1 Date of death	8	Date	Format DD/MM/YYYY
icause	Main cause of death	Outcome Form Q.3.1 Cause of death	1	Integer	1 = Bleeding, 2 = Head injury 3 = Myocardial infarction 4 = Stroke 5 = Pulmonary embolism 6 = Multi organ failure 7 = Other
scauseother	Description of cause of death if entered as "Other"	Outcome Form Q.3.1 Other - describe	60	String	Free text
istatus	Status of patient at Outcome if alive	Outcome Form Q.3.2 Discharged/Still in this hospital now	1	Integer	1 = Discharged, 2 = Still in hospital now 3 = Transferred to other hospital NULL (blank) = missing data if patient alive at outcome
ddischarge	Date of discharge, transfer to other hospital or day 28 from randomisation	Outcome Form Q.3.2 Date of discharge/Date	8	Date	Format DD/MM/YYYY

Variable	Label	Comments	Max Length	Туре	Codes
icondition	Condition of patient at outcome if alive	Outcome Form Q3.3 IF ALIVE TICK ONE BOX THAT BEST DESCRIBES THE PATIENT'S CONDITION	1	Integer	1 = No symptoms 2 = Minor symptoms 3 = Some restriction in lifestyle but independent 4 = Dependent, but not requiring constant attention 5 = Fully dependent, requiring attention day and night NULL (blank) = missing data if patient alive at outcome
ndaysicu	Number of days spent in Intensive Care Unit	Outcome Form Q.4 a) Days in Intensive Care Unit	3	Number	Range 0 to 58 NULL (blank), 99 and 999 = missing data
bheadinj	Significant head injury Yes or No	Outcome Form Q.4 b) Significant Head Injury	1	Boolean	0 = No 1 = Yes NULL (blank) = missing data
bneuro	Neurosurgical operation Yes or No	Outcome Form Q.4 c) Operation site Neurosurgical	1	Boolean	0 = No 1 = Yes NULL (blank) = missing data
bchest	Chest operation Yes or No	Outcome Form Q.4 c) Operation site Chest	1	Boolean	0 = No 1 = Yes NULL (blank) = missing data
babdomen	Abdomen operation Yes or No	Outcome Form Q.4 c) Operation site Abdomen	1	Boolean	0 = No 1 = Yes NULL (blank) = missing data
bpelvis	Pelvis operation Yes or No	Outcome Form Q.4 c) Operation site Pelvis	1	Boolean	0 = No 1 = Yes NULL (blank) = missing data

Variable	Label	Comments	Max Length	Туре	Codes
bpe	Pulmonary embolism Yes or	Outcome Form	1	Boolean	0 = No
	No	Q5. Complications			1 = Yes
		Pulmonary Embolism			NULL (blank) = missing data
bdvt	Deep vein thrombosis Yes	Outcome Form	1	Boolean	0 = No
	or No	Q.5 Complications			1 = Yes
		Deep Vein			NULL (blank) = missing data
		Thrombosis			
bstroke	Stroke Yes or No	Outcome Form	1	Boolean	0 = No
		Q.5 Complications			1 = Yes
		Stroke			NULL (blank) = missing data
bbleed	Operation for bleeding Yes	Outcome Form	1	Boolean	0 = No
	or No	Q.5 Complications			1 = Yes
		Operation for			NULL (blank) = missing data
		bleeding			
bmi	Myocardial infarction Yes or	Outcome Form	1	Boolean	0 = No
	No	Q.5 Complications			1 = Yes
		Myocardial Infarction			NULL (blank) = missing data
bgi	Gastrointestinal bleed Yes	Outcome Form	1	Boolean	0 = No
	or No	Q.5 Complications			1 = Yes
		Gastrointestinal			NULL (blank) = missing data
		bleeding			
bloading	Complete loading dose of	Outcome Form	1	Boolean	0 = No
	trial treatment given Yes or	Q.6 a) Complete			1 = Yes
	No	loading dose given			NULL (blank) = missing data
bmaint	Complete maintenance	Outcome Form	1	Boolean	0 = No
	dose of trial treatment	Q.6 b) Complete			1 = Yes
	given Yes or No	maintenance dose			NULL (blank) = missing data
		given			
btransf	Blood products transfusion	Outcome Form	1	Boolean	0 = No
	Yes or No	Q.7 a) Blood			1 = Yes
		products transfusion			NULL (blank) = missing data

Variable	Label	Comments	Max Length	Туре	Codes
ncell	Number of units of red cell products transfused	Outcome Form Q.7 b) Units transfused in 28 days Red cell products	2	Number	Range 0 to 60
nplasma	Number of units of fresh frozen plasma transfused	Outcome Form Q.7 b) Units transfused in 28 days Fresh frozen plasma	2	Number	Range 0 to 60
nplatelets	Number of units of platelets transfused	Outcome Form Q.7 b) Units transfused in 28 days Platelets	2	Number	Range 0 to 87
ncryo	Number of units of cryoprecipitate transfused	Outcome Form Q.7 b) Units transfused in 28 days Cryoprecipitate	2	Number	Range 0 to 61
bvii	Recombinant Factor VIIa given Yes or No	Outcome Form Q.7 b) Units transfused in 28 days Recombinant Factor VIIa	1	Boolean	0 = No 1 = Yes NULL (blank) = missing data
iboxid	Treatment box number. In combination with the pack number forms the unique 6 digit ID number of the patient (e.g. 800081)	Patient Entry Box	4	Integer	Format 4-digit number starting 2,3,4,5,8, or 9
ipacknum	Treatment pack number. In combination with the box number forms the unique 6 digit ID number of the patient (e.g. 800081)	Patient Entry Pack	2	Integer	Format 2-digit number starting 2,3,4,5,8 or 9