Trauma Reception and Resuscitation - 'Time for a New Approach'

Submission date	Recruitment status No longer recruiting	Prospectively registered		
16/02/2005		[] Protocol		
Registration date	Overall study status Completed	[] Statistical analysis plan		
06/01/2006		[X] Results		
Last Edited	Condition category Injury, Occupational Diseases, Poisoning	Individual participant data		
31/01/2019				
06/01/2006 Last Edited	Completed Condition category	 [_] Statistical analysis plan [X] Results		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00164034

Secondary identifying numbers N/A

Study information

Scientific Title

Trauma resuscitation errors and computer-assisted decision support.

Acronym

TR&RP

Study objectives

The introduction of real-time computer prompted algorithms will result in a measurable reduction in management errors associated with reception and resuscitation of major trauma patients, demonstrating that a reduction in management errors translates into a reduction in morbidity and mortality.

Ethics approval required

Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Treatment, Randomized, Open Label, Active Control, Parallel Assignment, Safety/Efficacy Study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Traumatic injury

Interventions

A historical control to assess the Hawthorne effect. A randomised controlled trial comparing trauma resuscitation supported by real-time computer prompted algorithms against those without.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

The primary benefits will be:

1. The development of evidence-based algorithms for trauma resuscitation

2. The development of real-time, computer aided, data collection during trauma resuscitation

3. Testing the hypothesis that the introduction of real-time, computer-prompted algorithms will result in a measurable reduction in management errors associated with reception and resuscitation of major trauma patients

4. Demonstrating that a reduction in management errors translates into a reduction in morbidity and mortality

Secondary outcome measures

The secondary benefits will be:

1. Standardising, publishing and distributing resuscitation documentation, interventions and diagnoses

2. Critical evaluation of the cost-benefit of trauma resuscitation video audit

3. Rejuvenation of resuscitation research through the development of a standardised environment

Overall study start date

01/01/2005

Completion date

30/09/2007

Eligibility

Key inclusion criteria

1162 test and control trauma cases presenting to the Trauma Centre of the Alfred Hospital.

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants 1162

Key exclusion criteria

Stable trauma patients (i.e. pulse rate <100/minute, mean arterial pressure [MAP] >70 mmHg, Hb >70, temperature >35 °C and <37.5 °C, SpO2 >92%, Glasgow Coma Score [GCS] >13) undergoing secondary transfer from another hospital, where trauma occurred >6 hours prior to arrival, will be excluded.

Date of first enrolment

01/01/2005

Date of final enrolment 30/09/2007

Locations

Countries of recruitment Australia

Study participating centre The Alfred Hospital Emergency and Trauma Centre Prahran Australia 3181

Sponsor information

Organisation The Victorian Trauma Foundation (Australia)

Sponsor details

P.O. Box 2751 Melbourne Australia 3001 +61 (0)3 96646563 vtf@vtf.com.au

Sponsor type

Charity

Funder(s)

Funder type Charity

Funder Name

The Victorian Trauma Foundation and The Alfred Hospital - Bayside Health

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		01/08/2006		Yes	No
<u>Results article</u>	results	01/02/2011	31/01/2019	Yes	No