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Role of closed loop IntelliVent ventilation mode in head injury patients requiring mechanical ventilation

Submission date
18/06/2020

Recruitment status
No longer recruiting

Registration date
23/06/2020

Overall study status
Completed

Last Edited
22/06/2020

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Traumatic brain injury (TBI) represents the leading cause of morbidity and mortality in individuals under the age of 45 in the world. Ventilatory management of a brain-injured patient is challenging.
In this study IntelliVent ASV (Adaptive Support ventilation) mode ventilation is used for mechanically ventilating patients with head Injury and compared to patients with head Injury who are ventilated with conventional mode of ventilation (SIMV, Synchronized Intermittent mandatory ventilation).

Who can participate?
Head injury patients requiring mechanical ventilation

What does the study involve?
Patients were assigned to either IntelliVent ASV or SIMV and followed up for 48 hours.

What are the possible benefits and risks of participating?
Benefits: the role of IntelliVent in head injury patients secures better outcomes in terms of decreased morbidity and mortality. This means less ICU stay, early wean off, decreased Hospital stay. It also means decreased workload for doctors and staff alike (as it is automated)
RISKS the role of IntelliVent mode being superior on conventional modes proves the other patients were neglected (in terms of decreased therapeutic care)

Where is the study run from?
Pakistan Ordinance Factory Hospital

When is the study starting and how long is it expected to run for?
November 2018 to April 2019

Who is funding the study?
Pakistan Ordinance Factory Hospital

Who is the main contact?
Dr Sadia Imran, S.s.imran2723@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Sadia Imran

Contact details
Pakistan Ordinance Factory Hospital
House #4, Champa road, opposite sir Syed school
Central park area
Wah cantt
Pakistan
47070
+92 (0)3448869927
S.s.imran2723@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparative analysis of closed loop IntelliVent mode ventilation in head injury patients to conventional SIMV ventilation modes

Study objectives
Closed loop INTELLIVENT ASV mode secures better outcomes in head injury patients as compared to conventional mode (SIMV)

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/06/2017 by Ethical Review Committee (ERC) of P.O.F Hospital (The Quaid Avenue, Wah Cantt, 47040, Pakistan; +92 322 2054452; Imr59us81@hotmail.com), ref: none provided

Study design
Single centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Patients with head injury fulfilling the inclusion criteria were selected and randomly allocated into two groups. Informed consent was taken from all the patients falling in inclusion criteria. Randomization of patients was based on the sequence of admission in the ITC. Even-numbered patients were allocated automated closed-loop INTELLIVENT mode and odd-numbered of patients were given conventional SIMV mode. Patients were blinded of the allocation sequence. SpO2 was measured with a finger probe i.e., pulse plethysmography. The PETCO2 was measured by a mainstream capnograph connected to the ventilatory circuit. The PETCO2 was measured throughout ventilation. All ventilation parameters were noted at 6 hrs interval and averaged over 48hrs. The data was entered in the proforma.

Each patient was individually assessed and evaluated according to the departmental protocols. This included history, physical examination, GCS scoring, radiological investigations, serum and blood baseline investigations and arterial blood gases evaluation.

Intervention Type
Procedure/Surgery

Primary outcome measure
End tidal CO2 was measured as a primary outcome of effective ventilation. The ETCO2 was measured at 6 hrs interval and then averaged over 48 hrs and filled on the questionnaire. ETCO2 for first 48 hrs was taken as a measure of ventilation.

Secondary outcome measures

Prevention of secondary insult during stay assessed with variables as the length of ICU stay, ICU mortality and hospital mortality using patient records

Overall study start date
01/04/2017

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Head injury with rapidly deteriorating GCS within 24 hrs
2. Patients with GCS less than 8/15 requiring mechanical ventilation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. GCS of 3/15 with head injury
2. Blunt trauma to the chest
3. Lung pathologies
4. Extremes of ages, infants, neonates and elderly
5. Co-morbidities such as DM, HTN

Date of first enrolment
01/11/2018

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
Pakistan

Study participating centre

P.O.F Hospital (Pakistan Ordinance Factory Hospital)
Intensive Therapeutic Care department
The Quaid Avenue
Wah Cantt
Wah Cantt
Pakistan
47040

Sponsor information

Organisation
Pakistan Ordinance Factory Hospital

Sponsor details
House #4, Champa road, opposite sir Syed school
Central park area
Wah cantt
Pakistan
47070
+92 (0)51 905525 265
comdhosp@pof.gov.pk

Sponsor type
Hospital/treatment centre

Website
http://Www.hospital.pof.gov.pk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pakistan Ordinance Factory Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date

07/07/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request