ISRCTN11776777 https://doi.org/10.1186/ISRCTN11776777

To compare the sodium and potassium values on a simple, faster handheld device with that of a central lab machine -which is time-consuming, to identify any abnormal values and decide on quick treatment on patients coming to the emergency department

Submission date
03/06/2018

Recruitment status
No longer recruiting

Registration date
06/06/2018

Overall study status
Completed

Last Edited
02/04/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The area of the study is an emergency department, with patients presenting to emergency with acute/severe illnesses for example: chest pain (heart attacks), breathing difficulty (lung infections), stoppage of heart (cardiac arrest), brain strokes, poisoning are a few examples. This study aims to determine whether a handheld arterial blood gas analyser (ABG), which produces results more quickly and is therefore beneficial to an emergency department, is as accurate as the central lab autoanalyzer at measuring sodium (Na+) and Potassium (K+) electrolytes.

Who can participate?
Adults aged above 18 years presenting to the emergency department

What does the study involve?
Eligible participants are treated as per the normal protocols of treatment, this study does not alter their treatment, routine care, hospital stay or outcome in terms of life or death of the participant, as it is just an observational study. Participants have blood samples taken and measured using a handheld arterial blood gas analyser and the central lab autoanalyzer.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for participants in the study.

Where is the study run from?
NH Multispecialty Hospital (India)

When is the study starting and how long is it expected to run for?
April 2016 to November 2017

Who is funding the study?
Narayana Hrudayalaya Limited (India)

Who is the main contact?
Dr Talha Hussain (public)

Contact information

Type(s)
Public

Contact name
Dr Talha Hussain

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Contact details
Narayana Hrudulayala Pvt Ltd
NH Health city
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560100

Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Comparison of the point-of-care blood gas analyzer (ABG) versus the laboratory auto-analyzer (AA) for the measurement of electrolytes (Na+ and K+) in emergency department

Study objectives
The null hypothesis states that there is no significant difference between electrolytes measured (sodium and potassium) using a handheld arterial blood gas analyzer (ABG) compared to the central lab autoanalyzer.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Narayana Health Academics Ethics committee, 02/06/2016, ref: NHH/AEC-CL-2016-O57

Study design
A prospective observational cross-sectional cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Emergency medicine

Interventions
This prospective observational study with a sample size of 200 study is conducted in NH-Multispecialty Hospital, Bangalore, India, in the emergency department. 200 consecutive patients with paired (2) samples of Arterial (1) and Venous (1) blood are included.
The study period is 1 year. The values of sodium (Na+) and potassium (K+) are measured using both a handheld arterial blood gas analyzer (ABG) and the central lab autoanalyzer, and compared using the paired t-test using R software. All results are expressed in mean +/- standard deviation.

Intervention Type
Device

Primary outcome(s)
Sodium (Na+) and Potassium (K+) levels are measured from blood samples using a handheld arterial blood gas analyzer (ABG) and the central lab autoanalyzer at the time of sample, to compare the accuracy of results.

Key secondary outcome(s))
None

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. Age above 18 years of either sex.
2. Patients presenting to ED with:
2.1. Unresponsiveness, with cardiac arrest without brain death
2.2. Hypovolemia
2.3. Patient in any form of shock: Hypovolumeic , Cardiogenic , Distributive , Septic
2.4. Anticipated sepsis and septic shock
2.5. Acute altered mental status
2.6. Acute respiratory distress
2.7. ACS
2.8. Cardiac rhythm disturbances

2.9. Seizures
2.10. CVA
2.11. Symptomatic patient with drug overdose
2.12. Poisoning – unknown compound/known
2.13. Abnormal blood sugar levels RBS < 40 mg% or >250 mg% or high unrecordable/low unrecordable blood sugars, by digital glucometers using capillary finger prick RBS.
2.14. Encephalopathies
2.15. Cardiac failure
2.16. AKI/CKD with acute symptoms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Less than 18 years of age
2. Burns patients

Date of first enrolment
30/06/2016

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
India

Study participating centre
NH Multispecialty Hospital
No 1, Basanth Healthcare Center
Opposite HSR Club
HSR Layout
Sector 2
Bangalore
India
560102

Sponsor information

Organisation
Narayana Hrudayalaya Limited

ROR
https://ror.org/05kx1ke03

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Narayana Hrudayalaya Limited

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Talha Hussain (principal investigator), talh0910@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	06/06/2018	02/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes