

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/04/2019	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

ORCID ID
<http://orcid.org/0000-0002-5469-316X>

Contact details
Narayana Hrudulayala Pvt Ltd
NH Health city
Bommasandra
Anekal Taluk
Bangalore
India
560100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

See additional files

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 measure

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.

Secondary outcome measures

None

Overall study start date

03/04/2016

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: Hypovolemic , 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200 individuals

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

Sponsor details

NH Health City

258/A Bommasandra Industrial Area

Anekal Taluk

Bangalore

India

560099

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05kx1ke03>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Narayana Hrudayalaya Limited

Results and Publications

Publication and dissemination plan

Planned publication in International Journal of Emergency Medicine.

Intention to publish date

01/10/2018

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