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Copeptin as a novel diagnostic and prognostic marker in the management of neurological and neurosurgical patients with sodium imbalance

Submission date
11/10/2006

Recruitment status
No longer recruiting

Registration date
21/11/2006

Overall study status
Completed

Last Edited
02/09/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00390962

Protocol serial number
157/06

Study information

Scientific Title
Copeptin as a novel diagnostic and prognostic marker in the management of neurological and neurosurgical patients with sodium imbalance

Acronym
COSMOS - (Copeptin in OSMOregulation and Stress assessment)

Study objectives
Sodium imbalance is common and an adverse prognostic factor in hospitalised patients. However, identifying the causes of sodium imbalance is challenging in clinical practice. Levels of Anti-Diuretic Hormone (ADH) are elevated in patients with stroke correlating with disease severity and stress level; however, its measurement is cumbersome. ADH is derived from a larger precursor peptide along with Copeptin, which is a more stable peptide directly mirroring the production of ADH. Copeptin can be assayed readily in plasma. Early prognostic factors to predict in-hospital mortality and medium/long-term outcome in critically ill neurological patients, are helpful to guide and tailor early decisions on treatment, discharge from the intensive care unit and application of interventions to prevent deterioration of neurological functions.

The aim of this trial is to evaluate Copeptin as a diagnostic tool in disturbances of water homeostasis and prognostic tool to predict outcome in a well-defined cohort of stroke patients and patients undergoing intracranial surgery.

Study hypotheses:
1. Copeptin will improve the diagnostic accuracy to diagnose sodium imbalances as compared to routinely used markers.
2. Copeptin will be a reliable prognostic tool, dependent or independent of sodium imbalance, to predict short-term (i.e. in-hospital) and medium-term (i.e. three months) clinical outcome in stroke patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the local ethical review board (Ethics Committee of Basel [EKBB] ref. no.: 157/06).

Study design
Prospective, observational study.

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Sodium imbalance

Interventions
After informed consent, all routinely determined baseline data will be assessed including medical history, clinical items (i.e. neurological status, volume status, pulse rate, blood pressure, weight) and laboratory items (i.e. urine/serum osmolality, electrolytes, among others). All patients will have a follow-up with clinical and laboratory assessment until the day of discharge.

After three months, they will be followed-up by a structured telephone interview to assess outcome (mortality, morbidity, as assessed by the Modified Rankin Scale and Barthel index). Copeptin will be assessed in a batch analysis upon completion of the plasma asseveration.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Copeptin will improve the diagnostic accuracy to diagnose sodium imbalances as compared to routinely used markers (gold standard) and algorithms.
2. Copeptin will be a reliable prognostic tool, dependent or independent of sodium imbalance, to predict short-term (i.e. in-hospital) and medium-term (i.e. three months) clinical outcome in stroke patients.

Key secondary outcome(s))
1. Comparison of copeptin with other risk scores and factors (cerebrovascular, National Institute of Health and Stroke Scale [NIHSS])
2. Comparison of copeptin with other biomarkers (Brain Natriuretic Peptide [BNP], Procalcitonin [PCT], endothelin) in light of the first endpoint

Completion date
06/11/2007

Eligibility

Key inclusion criteria
1. All consecutive patients who are admitted to the emergency department with an ischaemic or haemorrhagic stroke or Transient Ischaemic Attack (TIA) according to the World Health Organization criteria with symptom onset within the last three days
2. All consecutive patients who undergo intracranial surgery due to:
a. pituitary tumors
b. IntraCerebral Haemorrhage (ICH)
c. SubArachnoidal Haemorrhage (SAH)
d. chronic subdural haematoma
e. head trauma with contusio cerebri
f. intracranial abcesses

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Patients without informed consent

Date of first enrolment
06/11/2006

Date of final enrolment
06/11/2007

Locations

Countries of recruitment
Switzerland

Study participating centre
Division of Endocrinology, Diabetes and Clinical Nutrition
Basel
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Sponsor information

Organisation
University Hospital Basel (Switzerland)

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Other

Funder Name

Privately funded trial by the Principal Investigator of this trial.

Results and Publications

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?
Results article		01/12/2009	02/09/2021	Yes	No
Results article		21/09/2010	02/09/2021	Yes	No
Results article		01/05/2013	02/09/2021	Yes	No
Results article		29/07/2014	02/09/2021	Yes	No