

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

☐ Prospectively registered

☐ Protocol

Registration date

21/11/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

02/09/2021

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Mira Katan

Contact details

Division of Endocrinology, Diabetes and Clinical Nutrition

University Hospital Basel

Petersgraben 4

Basel

Switzerland

4051

+41 (0)61 265 2525

katanm@uhbs.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00390962

Secondary identifying numbers

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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet**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 measure

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.

Secondary outcome measures

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

Overall study start date

06/11/2006

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 abscesses

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

400 - 500

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

Switzerland

4051

Sponsor information

Organisation

University Hospital Basel (Switzerland)

Sponsor details

c/o Professor Beat Mueller
Division of Endocrinology
Diabetes and Clinical Nutrition
Petersgraben 4
Basel
Switzerland
4031
+41 (0)61 265 2525
happy.mueller@unibas.ch

Sponsor type

Hospital/treatment centre

Website

<http://www.universitaetsspital-basel.ch/#>

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**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?
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