PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

**EFFECT OF FLUID COMPOSITION ON ELECTROLYTE, ACID-BASE AND FLUID HOMEOSTASIS
IN PATIENTS EARLY AFTER SUBARACHNOID HEMORRHAGE**

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Two different kinds of fluid therapy was applied for patients with subarachnoidal hemorrhage. The hypothesis was, that these different kinds of fluids could affect electolyte balance (like natrium).

Brief Summary in Scientific Language

Serum electrolytes and fluid balance are frequently abnormal in patients after subarachnoid hemorrhage (SAH). The aim of this study was to evaluate early electrolyte and water homeostasis in these patients using two different fluid regimens.

Organizational Data

- DRKS-ID: **DRKS00003446**
- Date of Registration in DRKS: **2011/12/29**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **247/07 , Kantonale Ethikkommission Bern (KEK)**
  Postfach 56
  Murtenstrasse 31
  3010 Bern
  Schweiz
  URL:http://www.kek-bern.ch/kontakt.html

Secondary IDs

- Universal Trial Number (UTN): **U1111-1126-7247**

Health condition or Problem studied

- ICD10: **I60 - Subarachnoid haemorrhage**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>Normal saline and hydroxyethyl starch dissolved in normal saline(Voluven)were administered I.V for volume therapy according to clinical signs of hypovolemia as follows: low blood pressure and/or low urinary output(<0.5ml/kg/h) in the presence of low peripheral skin temperature, and/or decreased capillary refill or central/peripheral venous filling. The fluids used were blinded.</style>
- Arm 2: <style fontName='DejaVu Sans' isBold='true'>Balanced crystalloid and colloid solutions (Ringerfundin and Tetraspan) were administered administered I.V for volume therapy according to clinical signs of hypovolemia as follows: low blood pressure and/or low urinary output(<0.5ml/kg/h) in the presence of low peripheral skin temperature, and/or decreased capillary refill or central/peripheral venous filling. The fluids used were blinded.</style>

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Serum electrolyte and water homeostatis during the first 48h after randomization. Serum and urine electrolytes, kidney parameters, acid-base status and fluid balance was measured at baseline, 24h and 48h

Secondary Outcome

Fluid balance after therapy and outcome at discharge, length of stay in hospital

Countries of recruitment

- CH **Switzerland**

Locations of Recruitment

- University Medical Center **Department of Intensive Care Medicine, Inselspital, Bern**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2008/01/16**
- Target Sample Size: **36**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients more than 18 years old with acute subarachnoid hemorrhage. Evaluated by an independent physician prior to study start and with defeffed written informed consent within 48h after admission to ICU.

Exclusion criteria

age<18

Addresses

- **Primary Sponsor**

  Dept.of Intensive Care Medicine, University Hospital of Bern, Inselspital

Primary Sponsor

Dept.of Intensive Care Medicine, University Hospital of Bern, Inselspital
Mr. Professor Stephan Jakob
3010 Bern
Switzerland

Telephone: **+41 (0)31 632 41 44 oder +41 (0)31 632 53 00**
Fax: **[---]***
E-mail: **Stephan.Jakob at insel.ch**
URL: **[---]***

■ **Contact for Scientific Queries**

Department of Intensive Care Medicine, Univ.Hospital Bern, Inselspital
Mr. Professor Stephan Jakob
Freiburgstrasse
3010 Bern
Switzerland

Telephone: **+41 (0)31 632 41 44 oder +41 (0)31 632 53 00**
Fax: **+41316329644**
E-mail: **Stephan.Jakob at insel.ch**
URL: **[---]***

■ **Contact for Public Queries**

Dept.of Intensie Care Medicine, University Hospital of Bern, Inselspital
Mr. Professor Stephan Jakob
Freiburgstrasse
3010 Bern
Switzerland

Telephone: **+41 (0)31 632 41 44 oder +41 (0)31 632 53 00**
Fax: **+41316329644**
E-mail: **Stephan.Jakob at insel.ch**
URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Supported by an unrestricted grant from BBraun Medical AG, Sempach, Switzerland
6204 Sempach
Switzerland

Telephone: **[---]***

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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2010/05/04**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*