CTU News Archive 2008

11.11.2008 13:01

Die Gewinnerin des diesjährigen JF de Quervain Award steht fest.

Der JF de Quervain Award 2008 wurde an Dr. med. Vanessa Martine Banz verliehen.

Preisträgerin:

Vanessa Martine Banz, geboren 30.5.1977
Medizinstudium in Paris und Basel (Abschluss 2001)
2002-2005 Allgemeinchirurgie in Kantonsspitälern in Olten und Luzern
seit 2006 in der Allgemeinchirurgie des Inselspital (seit 2007 Stv. Oberärztin)
seit 2008 FMH Viszeralchirurgie

Titel:

Diverting loop ileostomy: rod versus no rod. A multicentre randomised controlled trial [Passageres doppelläufiges Ileostoma mit oder ohne Reiter: eine multizentrische, randomisierte kontrollierte Studie]

Ein provisorischer künstlicher Darmausgang (doppelläufiges Stoma) wird bei Operationen des Dickdarms häufig temporär zur Entlastung der operierten Darmabschnitte angelegt. Die Anlage eines solchen Darmausgangs mit Hilfe eines sogenannten Reiters, der unter der geöffneten Darmschlinge liegt und das Zurückgleiten der Schlinge in den Bauchraum verhindert, gilt als Standardverfahren. Der Reiter wird meist nach 10-14 Tagen entfernt, trotzdem kann die Verwendung des Reiters zu erheblichen, für die Patientinnen und Patienten belastenden Schwierigkeiten bei der Verwendung von Stomabeuteln führen, von Hautirritationen bis hin zum Absterben einzelner Darmabschnitte. Aus diesem Grund wurden verschiedene Techniken entwickelt zur Anlage eines künstlichen Darmausgangs ohne Reiter.

Das mit dem J.F. de Quervain Preis ausgezeichnete Projekt ist eine pragmatische multizentrische, randomisierte kontrollierte, zweiarmige Studie, in der die Anlage eines künstlichen Darmausgangs mit Reiter als Standardverfahren mit der Anlage eines künstlichen Darmausgangs ohne Reiter verglichen wird. In die Studie werden 180 Patienten, welche einen künstlichen Darmausgang benötigen, eingeschlossen. Um den Erfolg des neuen Verfahrens zu messen, wird das Auftreten von Komplikationen des künstlichen Darmausgangs zwischen Patienten mit und ohne Reiter verglichen. Erste Ergebnisse der Studie werden in drei Jahren erwartet.

16.10.2008 11:40

Inaugural-Symposium of CTU Bern at the Clinical Research Day

Wednesday, November 5, 2008, 14:30, Langhans Auditorium, Institute of Pathology, University of Bern, Murtenstrasse 31, Bern

14:30
The state of clinical research in Switzerland and the role of industry
Prof. Matthias Egger, Director, Institute of Social and Preventive Medicine, University of Bern

14:55
Reporting the results of research: should funders and ethics committees be accountable?
Dr Davina Ghersi, Coordinator, International Clinical Trials Registry Platform, WHO, Geneva

15:20
Horse races, clinical trials, and meta-analyses: don't stop too early!
Prof. Christian Gluud, Director, Copenhagen Trial Unit, Denmark

The Symposium is hosted by the Department of Clinical Research of the University of Bern as part of the Clinical Research Day. After a coffee break, the Clinical Research Day continues as follows.

16:00
Submission, peer review and publication ethics: insights into editorial decision making
Dr Stuart Spencer, Executive Editor, The Lancet, London

16:45
How scientific is clinical research?
Prof. Ernst Peter Fischer, Professor or the History of Science, University of Konstanz, Germany

17:30
Award presentations

18:15
Reception

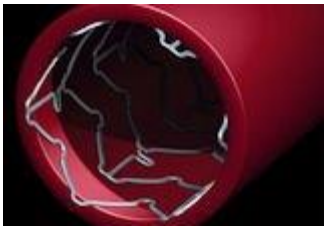
The Symposium is organised in collaboration with the Institute of Social and Preventive Medicine and the Department of Clinical Research of the University of Bern. No registration required.

See separate information at http://www.dkf.unibe.ch for a detailed programme of the Clinical Research Day.

02.09.2008 08:59

Studies on the safety and effectiveness of drug-eluting stents published simultaneously in the Lancet and the BMJ

Two papers by CTU Bern and ISPM on the safety and effectiveness of drug-eluting stents published simultaneously in the Lancet and the BMJ.



Simultaneously with talks by Stephan Windecker and Peter Jüni on the safety and effectiveness of drug-eluting stents at the European Society of Cardiology Meeting in Munich, two papers by CTU Bern and ISPM appeared in the Lancet and in the BMJ. The article by Stephan Windecker, Simon Wandel, Peter Jüni and colleagues in the Lancet describes a randomised controlled multi-centric non-inferiority trial in 1700 patients with chronic stable coronary artery disease or acute coronary syndromes comparing a novel drug-eluting stent using a biodegradable polymer with the currently most effective drug-eluting stent, which uses a non-degradable polymer. **»»**

The article by Christoph Stettler, Sabin Allemann, Simon Wandel, Stephan Windecker, Peter Jüni and colleagues in the BMJ describes results from a network meta-analysis comparing the effectiveness and safety of sirolimus eluting, paclitaxel eluting and bare metal stents in people with and without diabetes. **»»**

15.08.2008 13:25

Point-of-care coagulation monitoring trial

By: Sven Trelle

A randomized-controlled trial evaluating the effectiveness of point-of-care coagulation monitoring in combination with an algorithm to optimize transfusion strategies during surgery started recruitment. This study is a randomized-controlled, patient-blinded parallel group trial comparing the effects of point-of-care coagulation monitoring in combination with an algorithm to optimize transfusion strategies with standard care during surgery. Overall, 220 patients will be recruited at the Department of Anesthesiology and Pain Therapy of Bern University Hospital (Inselspital). Recruitment is planned to end in September 2010.

Short title

POC-RCT

ClinicalTrials.gov Identifier

NCT00656396

Official title

Does point of care coagulation testing reduce the transfusion of non-erythrocyte blood products in patients undergoing major surgery? A randomized-controlled trial.

Status

Recruiting

Role of CTU Bern

Consulting
Protocol development
Grant application
Database development
Randomization
Data management
Monitoring
Statistical analysis

Objective

To determine the effectiveness of point of care coagulation monitoring in combination with an algorithm to optimize transfusion strategies.

Study design

Design: Randomized-controlled trial
Data collection: Prospective
Allocation: Randomized
Blinding: Patient- and outcome-assessor blind
Number of study groups: Two-arm study
Study centers: Single-center
Study phase: Phase III
Number of participants: 2 x 110

End of follow-up: March 2011

Eligibility

- Men and women between 18 and 90 years of age undergoing major surgery

- Estimated blood loss during surgery exceeds 20% of the individual's estimated normal total blood volume or anesthesiologist or surgeon intend to give fresh frozen plasma

Primary outcomes

Relative risk of receiving any fresh frozen plasma in-hospital, defined as the administration of at least 0.5 units of fresh frozen plasma received between randomization and post-operative discharge from hospital

Interventions

All patients will receive allogenic blood products according to pre-defined transfusion algorithms, one for fresh frozen plasma and one for platelets. Landmarks of the algorithms include: 1) blood loss of more than 20%, 2) PT of less than 50%, 3) platelet count of less than 50.000 per liter, 4) clinical observed bleeding and judged by the attending physician. Experimental intervention: Prothrombin testing in the operating room using a point of care device (Coagucheck XS Plus® Roche Diagnostics, Basel, Switzerland)

Control intervention: Prothrombin testing centrally in hematology laboratory (standard care)

Principal investigator

Robert Greif (Department of Anesthesiology and Pain Therapy, Bern University Hospital (Inselspital))

Sponsor

Bern University Hospital (Inselspital)

10.07.2008 12:04

JF de Quervain Prize 2008 (CHF 25'000.-)

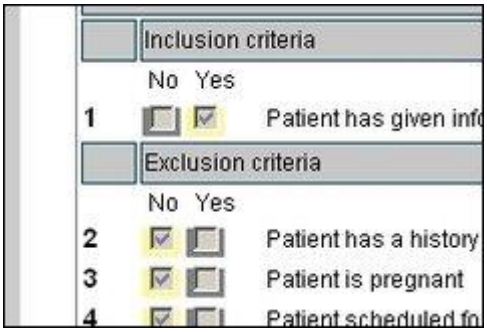
JF de Quervain Award

The JF de Quervain Award is granted annually by CTU Bern at the Faculty of Medicine's Clinical Research Day for the best patient-oriented clinical study proposal. The recipient receives a Clinical Reserach Fellowship at CTU Bern and CHF 25'000.- to pay a part of the researcher's salary. Clinical researchers under 40 years of age affiliated with the Faculty of Medicine, University of Bern are invited to submit patient-oriented clinical study proposal.

05.06.2008 14:36

SINATRAS, the EDC software developed by SAKK, used for collection of clinical data and administration of trials at CTU Bern

SINATRAS is a web based clinical trial software for Electronic Data Capture (EDC) that has been developed by the Swiss Group for Clinical Cancer Research (SAKK)



In the scope of the collaboration between SAKK and CTU Bern, Sinatras has been adapted to the needs of CTU Bern and is now also being used for clinical trials carried out by CTU Bern.

Using SINATRAS, clinical trial data collection can be implemented rapidly. As it is web-based, it is suitable for multi-center studies. Validity checks on the eCRF forms detect errors or suspicious outliers so that these can be corrected immediately. In addition, SINATRAS also contains integrated monitoring functionalities including a query administration.

Data entry for the first trial using Sinatras was launched on May 1st 2008.