

# CTU News Archive 2010

01.11.2010 08:07

## Peter Jüni new professor of clinical epidemiology

For the newly created position of a Full Professor of Clinical Epidemiology at the Faculty of Medicine of the University of Bern, the Board of Directors of the University has appointed Prof. Peter Jüni. He will assume this post on November 1, 2010.



Peter Jüni (43) grew up in Bern and studied medicine at the University of Bern. After graduation in 1995, he worked as a specialist registrar in internal medicine and rheumatology in various Bernese hospitals. A number of research stays took him to the Department of Social Medicine at the University of Bristol (England). From 2002 onwards, he was a Senior Research Fellow, initially at the Department of Rheumatology, Clinical Immunology and Allergology at the Inselspital, later at the Institute of Social and Preventive Medicine of the University of Bern where he received Venia docendi (Habilitation) in 2005 and was promoted to Associate Professor of Clinical Epidemiology in 2009. The focus of Peter's research is on the epidemiology and treatment of osteoarthritis and coronary heart disease, and on research methodology.

**Für die an der Medizinischen Fakultät neu geschaffene ausserordentliche Professur in klinischer Epidemiologie hat die Universitätsleitung Prof. Peter Jüni gewählt. Er tritt seine Stelle am 1. November 2010 an.**

Peter Jüni (43) ist in Bern aufgewachsen und hat an der Universität Bern Medizin studiert. Nach dem Staatsexamen im Jahre 1995 arbeitete er bis 2001 als Assistenzarzt in Innerer Medizin und Rheumatologie in verschiedenen Berner Spitälern. Mehrere Forschungsaufenthalte führten ihn wiederholt ans Department of Social Medicine der Universität Bristol (England). Ab 2002 war er als wissenschaftlicher Oberarzt zuerst in der Klinik für Rheumatologie, klinische Immunologie und Allergologie des Inselspitals, später am Institut für Sozial- und Präventivmedizin der Universität Bern tätig, wo er 2005 habilitierte und 2009 zum assoziierten Professor für klinische Epidemiologie befördert wurde. Im Zentrum seiner Forschungstätigkeit stehen die Epidemiologie und Therapie der Arthrose und der koronaren Herzkrankheit und Fragen zur Forschungsmethodik.

20.10.2010 08:45

## **SwAPP How2GCP e-learning tool**

**This e-learning tool from the Swiss Association of Pharmaceutical Professionals is an internet-based platform for modern GCP training**

The How2GCP e-learning tool from the Swiss Association of Pharmaceutical Professionals is a process-oriented training course in English with integrated texts of the VKlin in German and French. It is based on GCP principles, as defined in the ICH-Guidelines and VKlin.

Access to this tool can be provided by CTU Bern.

20.10.2010 08:32

## **EMA launches its new website**

**The European Medicines Agency unveiled its new corporate website at [www.ema.europa.eu](http://www.ema.europa.eu)**



The site has been completely redesigned and rebuilt to optimize usability for the Agency's key online audiences and build on existing activities to improve openness and transparency.

The Agency website now receives an average of half a million unique visits per month and is a key resource for patients, healthcare professionals, regulators and those interested in the regulation and safety of medicines in the European Union.

### **Some of the website's new features include:**

- Quick medicine searches: Allows you to search for human and veterinary medicines by name and active substance and for herbal medicinal substances by name
- An online library: Enables you to search for all Agency documents currently online through a search on title and date published online
- Improved navigation: More intuitive labelling and improved organisation of content so that browsing is quicker for all audience groups
- Audience landing pages: Flags information of specific value to different key users
- Online calendar and news search: Allows you to keep up to date with the latest news and events at the Agency  
RSS feeds: Brings information straight to you as soon as it is published online

Through 2010 and 2011 the Agency will continue to work on improving the website by increasing the use of multimedia and improving search functionalities.

29.09.2010 08:59

## Upcoming training courses 2011

### Clinical Investigators I and Clinical Investigators II

#### Clinical Investigators I: Basic GCP & clinical research training

**24. January 2011**

This course provides prospective clinical investigators with essential knowledge of clinical research. It covers elements of Good Clinical Practice and of other regulatory and ethical requirements providing intensive and practice-oriented training for clinical research professionals.

This course fulfills the published requirements accepted by AGEK, SAMW, SMIFK, SIWF, SGCI, Swissmedic and SCTO for the training **sub-investigators**. Participants finishing the Basic and Advanced training course fulfil the requirements of Article 8, par. 1 lit. b and Article 10 par. 2 lit. oClin

In addition attendance is acknowledged with:

- 5 credits (category B, seminars) as continuing medical education for physicians in medical oncology and haematology (SGH, SGMO)
- 5.5 credits of the Swiss Association of Pharmaceutical Professionals (SwAPP)

Course description & registration form >>

#### Clinical Investigators II: Advanced GCP & clinical research training

**9 – 10. June 2011**

This course provides prospective clinical investigators with intense, highly practice-oriented knowledge of Good Clinical Practice and of other regulatory and ethical requirements, and the knowledge and skills for developing study protocols, conducting clinical studies and publishing study reports (including sponsor or investigator initiated studies). Lectures will be complemented with workshops allowing participants to apply their knowledge within practical group exercises and interactive discussions

This course fulfills the published requirements accepted by AGEK, SAMW, SMIFK, SIWF, SGCI, Swissmedic and SCTO for the training of **investigators and sponsor-investigators**. Participants finishing the Basic and Advanced training course fulfil the requirements of Article 8, par. 1 lit. b and Article 10 par. 2 lit. oClin

In addition attendance is acknowledged with:

- 5 credits (category B, seminars) as continuing medical education for physicians in medical oncology and haematology (SGH, SGMO)
- 11 credits of the Swiss Association of Pharmaceutical Professionals (SwAPP)

Course description & registration form >>

01.09.2010 15:05

## **New address**

**CTU Bern has moved to Finkenhubelweg 11, 3012 Bern**

How to find us [>>](#)

22.02.2010 12:04

## **Clinical Investigators II: Advanced GCP & clinical research training course**

**A two-day training course aims at providing investigators with the knowledge to set-up their own project.**

The course will consist of a series of lectures supplemented with workshops.

Key topics covered in this course include.

- Developing research objectives
- Basic statistical concepts
- Uncontrolled studies
- Randomized controlled trials
- Diagnostic accuracy studies
- Ethical and legal principles
- Good Clinical Practice guidelines and quality assurance
- Practical implementation issues in clinical research
- Patient information and consent
- Data collection and handling
- Clinical events and safety issues
- Critical appraisal of RCTs
- Research publication

**Date:** 9 - 10 June 2010

## **Trans-Fatty Acids (TFA) Trial**

### **Do ruminant trans fatty acids have the same effect on cardiovascular risk markers as industrial trans fatty acids?**

This randomized-controlled, double-blind trial comparing three different types of nutrition in healthy volunteers aims at assessing the effect of ruminant trans fatty acids on cardiovascular risk markers. Healthy men and women between 45 and 65 years of age are eligible for this study.

#### **Official title**

Randomized-Controlled Trial to Assess the Effects of Different Trans-Fatty Acids on Endothelial Function in Humans

#### **Objectives**

To compare a diet rich in trans fatty acids (TFA) from ruminant sources with a diet rich in TFA from hydrogenated vegetable oils (PHVO) in regard to their effects on cardiovascular risk markers (endothelial function, blood lipids, inflammation and coagulation parameters in the blood).

#### **Study design**

Design: Basic Science, Randomized, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Parallel Assignment, Efficacy Study

Study centers: Cardiovascular Prevention and Rehabilitation, Bern University Hospital

Number of participants: 205

#### **Eligibility**

Inclusion Criteria:

- age 45-65
- body mass index 20-30 kg/m<sup>2</sup>
- willingness to hold physical activity constant over study duration
- written informed consent

Exclusion Criteria

- smoking
- hypertension (> 90/140 mm Hg)
- hypotension (men < 115 mm Hg; women < 105 mm Hg)
- adipositas (BMI =/> 30 kg/m<sup>2</sup>)
- vegan
- infections in the last 6 weeks
- allergy for food (e.g., milk)
- pregnancy
- diabetes (elevated fasting blood glucose level)
- clinical known coronary diseases
- acute and/or chronic medication (incl. contraceptive)
- abnormal kidney function
- abnormal liver function
- known cardiac arrhythmia (e.g., atrial fibrillation)
- blood parameters (ALAT, Creatinin, Hb, Calcium, CRP) in range

#### **Primary outcomes**

Endothelial function using flow-mediated dilation

## **Interventions/Exposures**

Dietary Supplement: diet enriched with industrial trans fatty acids

Dietary Supplement: diet enriched with ruminant trans fatty acids

Dietary Supplement: diet without any trans fatty acids

## **Timeframe**

July 2009 - October 2010

## **Sponsor**

Inselspital, Bern University Hospital

## **Responsible Party:**

Study Director: Hugo Saner, Prof. Dr. med, Cardiovascular Prevention and Rehabilitation, Inselspital, Bern University Hospital, Switzerland

Study Director: Alexandra Schmid, Dipl. oec. troph., Agroscope Liebefeld-Posieux Research Station ALP, Posieux, Switzerland

Principal Investigator: Anja S Trepp, MSc, Cardiovascular Prevention and Rehabilitation, Inselspital, Bern University Hospital, Switzerland

Email: [anja.trepp\[at\]insel.ch](mailto:anja.trepp[at]insel.ch)

## **Funding**

- Inselspital, Bern University Hospital
- Forschungsanstalt Agroscope Liebefeld-Posieux ALP
- CTU Bern, Clinical Trials Unit
- Schweizer Herzstiftung
- Bundesamt für Landwirtschaft
- Emmi Schweiz AG

## **Collaborators**

- Inselspital, Bern University Hospital
- Agroscope Liebefeld-Posieux Research Station ALP, Posieux, Switzerland
- CTU Bern, Clinical Trials Unit
- Schweizer Herzstiftung
- Bundesamt für Landwirtschaft
- Emmi Schweiz AG

## **Role of CTU Bern**

- Consulting
- Case report form design
- Database development
- Randomization
- Data management
- Statistical analysis