UNIVERSITÄT BERN

CTU News Archive 2016

Financial support for research databases of the Inselspital

As of 1.1.2017, CTU Bern will again be able to give a discount for research databases of the Inselspital Bern. The discount amounts to up to CHF 3'000.- per study and can be used for studies that are not industry sponsored. The funds are taken from the core funding that the CTU Bern receives from the Direktion Lehre und Forschung (DLF) of the Inselspital. Insel researchers can find details on the funding on the Insel Intranet.

OPERAM trial now open for recruitment

The OPERAM trial funded by a HORIZON 2020 grant started recruitment this week at the Department of Internal Medicine at the Inselspital Bern.

Drug-related morbidity and mortality is an increasing problem for European health-care systems. It is estimated that every third hospital admission could be due to unnecessary interventions and inappropriate medications. Multimorbidity, polypharmacy, and old age are important risk factors for “drug-related hospital admissions”.

The clinical trial OPERAM, led by Prof. Rodondi from Inselspital Bern and University of Bern, evaluates whether a software-based systematic drug review can reduce these admissions. OPERAM is a multicenter, randomized-controlled trial with participating university hospitals in Bern, The Netherlands, Belgium, and Ireland. The trial started recruitment this week and the first patient was included in Bern. CTU Bern is responsible for the trial coordination, data management, statistics, and monitoring. More information can be found here.

ICH adopted the Integrated Addendum to the Good Clinical Practice (GCP) Guideline

On November 30th, 2016 the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) announced the adoption of the Integrated Addendum to the Good Clinical Practice (GCP) Guideline E6(R2). ICH states that the "guideline has been amended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure human subject protection and reliability of trial results". The amendment will now be implemented by ICH members through national and regional guidance. The main changes by the amendment cover the following areas:

- Perhaps the most significant change is the requirement to adopt risk management principles in a Quality Management System and in monitoring of a trial.
- The amendment also includes the principle for sponsors to address detected significant non-compliance through root cause analysis, and prevention of reoccurrence (CAPA plan).
- Clarifications regarding electronic data capture.
- Enhanced oversight requirements for investigators and sponsors.

The updated guideline E6(R2) can be found here.

The CTU Lecture on 17.01.2017 will introduce the new addendum and the most important changes.

New member of staff: Marie Roumet

After completing her studies in biology and ecology with a focus on genetics and biostatistics at the University of Montpellier, Marie completed a PhD in plant biology. Afterwards, she worked as a postdoctoral researcher at the ETH Zürich for more than 4 years. She joined CTU as a Senior Statistician and will replace Roger Schürch who will be leaving CTU soon taking on a position as assistant professor at Virginia Tech, Blacksburg/VA.

New Certificate of Advanced Studies in Clinical Epidemiology

The University of Bern offers a new Certificate of Advanced Studies in Clinical Epidemiology. Participants will learn the necessary methods to plan, conduct and communicate clinical research projects.

Clinical epidemiology is a sub-specialty of epidemiology which studies both the distribution and determinants of health-related events in the population. The CAS also covers how to use biostatistical methods for data analysis including using a data analysis software.

The course modules are organized by the Institute of Social and Preventive Medicine in close collaboration with other institutes of the University of Bern conducting clinical research including CTU Bern.

The CAS comprises approximately 10 course modules and involves approximately 350-450 hours of work and leads to the acquisition of 15 ECTS points. Details concerning the modules are still under development.

Source & further information

Call for Entries: SPRINT Data Analysis Challenge

In order to demonstrate the potential benefits of clinical trial data sharing and transparency, the New England Journal of Medicine (NEJM) has launched the SPRINT Data Analysis Challenge. The Challenge encourages healthcare professionals, researchers and scientists from around the world to use the dataset underlying the SPRINT report, plus any other publicly available dataset, to identify a novel scientific or clinical result. You can find more information here.

Any researchers interested in the challenge and with idea(s) can contact CTU Bern immediately to discuss and plan the next steps (info@ctu.unibe.ch).

Recommendations for the construction and use of health-related registers

Registers with reliable data are becoming increasingly important in the healthcare sector. To contribute to the quality assurance, the organizations ANQ, FMH, H+, SAMW and unimedsuisse have jointly published recommendations for the construction and use of health-related registers. These include minimum standards for example on data protection and data quality. You can find The recommendations here.

Umfrage zur Einreichung über BASEC

swissethics ist interessiert an Ihrem Feedback zur Einreichung neuer Forschungsprojekte über BASEC.
swissethics hat dazu eine Umfrage gestartet, die Sie hier ausfüllen können.

CTU Newsletter September 2016

28.10.16

- IICT call: Drei erfolgreiche Projekte am Inselspital

- Die CI zieht um!

- Praktikum an der Clinical Investigation

- Ethikeinreichung via BASEC

- Neuer GCP Modulkurs

- Die nächsten Kurstermine und CTU Lectures

CTU Newsletter September 2016 (PDF, 360KB)

New template for the Annual Safety Report of IITs available

26.10.16 - Swissethics has published a new template of the Annual Safety Report for Investigator initiated trials (IITs) under the Clinical Trials Ordinance (ClinO). The template can be found and downloaded on the website of swissethics (Templates/Recommendations -> Procedures).

PDF document: http://www.swissethics.ch/doc/ab2014/ClinO_annual_safety_report.pdf

Word document: www.swissethics.ch/doc/ab2014/ClinO_annual_safety_report.docx

Researchers and study personnel needing assistance with the writing of the annual safety report may contact the CTU Bern monitoring and quality assurance team by sending us an e-mail or calling us at the e-mail address and phone number listed below:

- info[at]ctu.unibe.ch
- +41 31 631 33 72

Lessons Learned

25.10.16 - What is a Site Delegation & Signature Log and what purpose does it serve? Read more

Second IICT call by the SNSF: Submit your letter of intent by 1 September 2016

04.08.16 - In 2015, the SNSF introduced a special programme for Investigator Initiated Clinical Trials. The programme offers targeted support for independent, comprehensive clinical studies in order to meet major scientific and societal needs. The call is limited to prospective, randomised, controlled, interventional, multicentric studies of existing treatments on topics that are not in the industry focus and therefore insufficiently researched. The SNSF will evaluate the study proposals in consultation with an international panel.

For the 2016 call, issued on August 3 2016, the SNSF has a budget of CHF 10 million. This should, according to the SNSF, be sufficient to fund at least four studies.
The SNSF requires that data collection and quality assurance is in line with international standards. Therefore these processes should be supervised and supported by an academic institution such as a Clinical Trial Unit.
CTU Bern is looking forward to support and collaborate with researchers who are planning to submit a project. In case of interest, researchers are asked to contact CTU Bern as early as possible so that the CTU staff members can provide the best possible support.

- Data management, database: datamanagement@ctu.unibe.ch
- Quality assurance, Monitoring and Statistics, Methodology: info@ctu.unibe.ch

We are looking forward to many fruitful collaborations.

Important deadlines:
Submission of letter of intent:

1 September 2016, 5 p.m. Swiss local time

Submission of applications:

1 November 2016, 5 p.m. Swiss local time

Source & further information:
http://www.snf.ch/en/funding/programmes/iict/Pages/default.aspx

First IICT call by the SNSF: Three approved projects at the Inselspital Bern

22.07.16 - In August, the SNSF has launched the first call for independent, Investigator Initiated Clinical Trials (IICTs). With the IICT programme, the SNSF aims to promote clinical studies in areas that are not in the industry focus and therefore under-researched (e.g. rare diseases, paediatric diseases, therapy combinations, dosage reduction studies and rehabilitation measures).

The call has attracted wide interest among the clinical researchers in Switzerland and a total of 75 applications have been submitted to the SNSF. Of all the applications, nine have been approved. The clinical studies will be allocated a total of 12.6 million francs. Most of them will last between four and five years and involve 100 to 400 patients in 14 study centres.

With three approved applications, the clinical researchers at the Inselspital Bern have been highly successful. CTU Bern congratulates the successful research teams:

Claudio L. Basseti, Department of Neurology, Inselspital Bern:

Early Sleep Apnea Treatment in Stroke: A Randomized, Rater-Blinded, Clinical Trial of Adaptive Servo-Ventilation

Daniel Guido Fuster, Division of Nephrology, Inselspital Bern:

NOSTONE Trial - Randomized double-blind placebo-controlled trial assessing the efficacy of standard and low dose hydrochlorothiazide treatment in the prevention of recurrent calcium nephrolithiasis

This study plans to assess the efficacy of standard and low dose hydrochlorothiazide (HCTZ) treatment in the recurrence prevention of calcium containing kidney stones. More specifically the aim is to assess the dose-response relationship for three different dosages of HCTZ.

Markus Schwerzmann, Department of Cardiology, Inselspital Bern:

SERVE Trial - Effect of phosphodiesterase-5 inhibition with Tadalafil on SystEmic Right VEntricular function – a multi-center, double-blind, randomized, placebo-controlled clinical trial

This study assesses the effect of phosphodiesterase (PDE)-5 inhibition with Tadalafil (Adcirca®, manufacturer Eli Lilly) on the right ventricle (RV) function, exercise capacity and neurohumoral activation in adults with a systemic RV over a 3-year follow-up period.

CTU Bern collaborates closely with the division of nephrology and the department of cardiology and will actively support the study teams during the planning and conduct phase of their clinical trials.

A second IICT call will be launched by the SNSF in August 2016.

Source & further information:

http://www.snf.ch/en/funding/programmes/iict/Pages/default.aspx

GCP Refresher course on 7th of June

25.05.16 - On Tuedsay, June 7th 2016, CTU Bern offers a free half day course at the Inselspital for GCP certificate holders, who wish to refresh and update their good clinical practice knowledge.

All important information can be found here.

Results of CTU customer survey now available!

23.03.16

In January and February 2016, CTU Bern conducted a survey among customers from the Inselspital. The results of this survey are now available.

In January and February 2016, CTU Bern conducted a survey among customers from the Inselspital. The current survey was based on a similar survey conducted in 2012 to allow for comparisons and changes over time. It was implemented as a fully anonymous, web-based questionnaire.

550 persons were invited by e-mail to participate (4 reminders were sent to increase participation rate). Of these, 144 responded (25% response rate). About 75% have collaborated with CTU Bern and provided insights in how they view the quality of the collaboration.

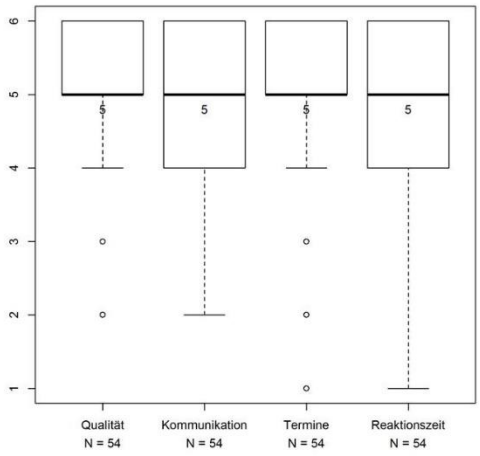
Overall, quality of the collaboration and of CTU staff was rated good. The full report can be found below.

Although the result of this survey is generally reassuring and satisfying, some areas for improvement have been identified and will be addressed in the coming months.

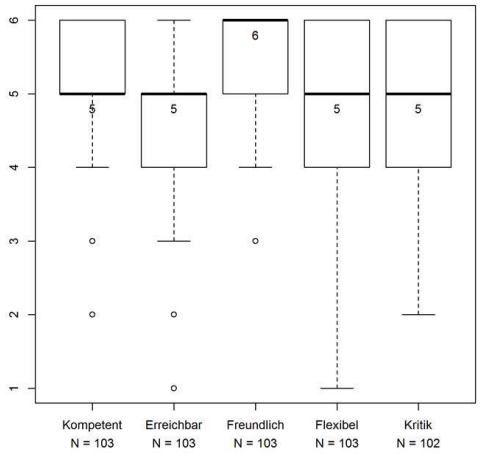
Many thanks to all participants!

2016 CTU Insel survey report (PDF, 435KB)

Illustrations



Feedback to collaboration

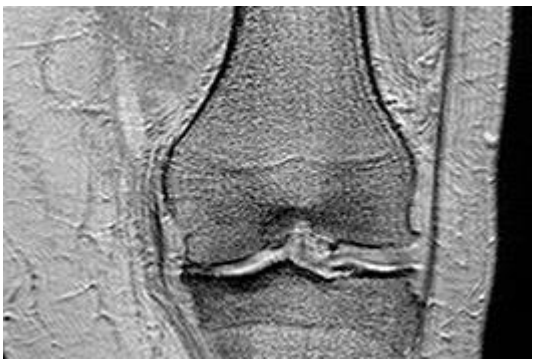


Feedback to CTU Staff

SCTO Symposium 2016:
Building up the future generation of clinical researchers

29.04.16 - Leading experts and stakeholders will discuss on 16 June 2016 in Lausanne the current opportunities and challenges as well as future perspectives to promote young physicians in the field of clinical research. Register now! Read more

The Lancet: Paracetamol ‘not clinically effective’ in treating osteoarthritis pain or improving physical function



Source of the following press release: The Lancet journals, London - 17.03.2016

In a large-scale analysis of pain-relief medication for osteoarthritis, researchers find that paracetamol does not meet the minimum standard of clinical effectiveness in reducing pain or improving physical function in patients with knee and hip osteoarthritis. Although paracetamol was slightly better than placebo, researchers conclude that, taken on its own, paracetamol has no role in the treatment of patients with osteoarthritis, irrespective of dose.

The study, published today in The Lancet, is the largest analysis of randomised trials of medical pain relief for osteoarthritis to date, and finds that diclofenac 150mg/day, a non-steroidal anti-inflammatory drug (NSAID), is the most effective short-term pain relief. However, the authors caution against long-term use of NSAIDs because of known side-effects.

Worldwide, 9.6% of men and 18% of women over the age of 60 have osteoarthritis. Estimates suggest that 26.9 million adults in the USA have the disease, and 8.75 million in the UK. Osteoarthritis is the leading cause of pain in elderly people. It can impair physical activity, which increases patients’ risk of obesity, cardiovascular disease, diabetes, and general ill-health.

Dr Sven Trelle from the University of Bern, Bern, Switzerland, and colleagues, pooled data from 74 randomised trials published between 1980 and 2015. With data from a total of 58556 patients with osteoarthritis, the study (a network meta-analysis) compared the effect of 22 different medical treatments and placebo on pain intensity and physical activity. The 22 treatments included various doses of paracetamol and seven different NSAIDs.

Paracetamol and NSAIDs are usually the first line treatment for mild to moderate pain management in osteoarthritis, but paracetamol is used more frequently in the long-term because of the cardiovascular and gastrointestinal side effects associated with long-term NSAID use.

The analysis found that all 22 preparations of medications, irrespective of dose, improved symptoms of pain compared with placebo. Although some doses of paracetamol had a small effect on improving physical function and decreasing pain, the effect was only slightly better than placebo, and did not reach the minimum clinically important difference (effect size of –0.17 vs. clinically important difference of -0.37). In comparison, diclofenac at the maximum

daily dose of 150 mg/day was most effective for the treatment of pain and physical disability in osteoarthritis (effect size –0.57), and superior to the maximum doses of frequently used NSAIDs, including ibuprofen, naproxen, and celecoxib.

According to Dr Trelle, "NSAIDs are usually only used to treat short-term episodes of pain in osteoarthritis, because the side-effects are thought to outweigh the benefits when used longer term. Because of this, paracetamol is often prescribed to manage long-term pain instead of NSAIDs. However, our results suggest that paracetamol at any dose is not effective in managing pain in osteoarthritis, but that certain NSAIDs are effective and can be used intermittently without paracetamol.""NSAIDs are some of the most widely used drugs for patients with osteoarthritis. There is a range of different drugs at different dosages that doctors can prescribe, but patients often switch between drugs, or stop taking them because the first one they use hasn't sufficiently helped control the pain. We hope our study can help better inform doctors about how best to manage pain in this population." The length of follow-up in most of the included trials was 3 months or less, and the authors acknowledge that other studies which include longer-term follow-up may be necessary. Although the overall number of patients included in the analysis was large, the number of individual trials assessing individual doses was still low.

Writing in a linked Comment, Professor Nicholas Moore and colleagues from the Department of Pharmacology at the University of Bordeaux, Bordeaux, France, point to the limitations of the study: "Other widely used NSAIDs were not included in this meta-analysis, probably because no recent trials have been done of these drugs or because any recent trials that did assess them were too small. These omissions are unfortunate because these drugs might be as effective but much cheaper than the newest drugs." He concludes: "the most remarkable result is that paracetamol does not seem to confer any demonstrable effect or benefit in osteoarthritis, at any dose. This finding is not entirely unexpected. Paracetamol has been on the market for as long as most of us remember. Its efficacy has never been properly established or quantified in chronic diseases, and is probably not as great as many would believe. Its safety is also questioned, not just in overdose." He adds: "Many patients could be suffering needlessly because of perceived NSAIDs risks and paracetamol benefits (which might not be real). Perhaps researchers need to reassess both these perceptions (or misconceptions) and the use of other analgesic options that have been discarded over time, such as dipyrone."

Bruno R da Costa, PhD, Stephan Reichenbach, MD, Noah Keller, MMed, Linda Nartey, MD, Simon Wandel, PhD, Prof Peter Jüni, MD, Dr Sven Trelle, MD: ***Effectiveness of non-steroidal anti-inflammatory drugs for the treatment of pain in knee and hip osteoarthritis: a network meta-analysis,*** **Lancet, 17.03.2016**

Abstract of the article: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30002-2/abstract

Tocilizumab effective for patients with giant cell arteritis

21.03.2016 - Giant cell arteritis is an immune-mediated disease of medium and large-sized arteries that affects mostly people older than 50 years of age. The study aimed to assess the efficacy and safety of tocilizumab in the first randomised clinical trial in patients with newly diagnosed or recurrent giant cell arteritis.

Overall, 30 patients were randomized, 20 to tocilizumab and 10 to placebo, to receive 13 infusions every 4 weeks. The primary outcome was the proportion of patients who achieved complete remission of disease at a prednisolone dose of 0·1 mg/kg per day at week 12. At week 12, 17 of 20 patients who had received tocilizumab achieved complete remission (85%) but only 4 of 10 patients who had received placebo (40%) – a risk difference of 65%, 95 confidence interval 36 to 94%). Seven (35%) patients in the tocilizumab group and five (50%) in the placebo group had serious adverse events.

The online version of the article can be found here:

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)00560-2/abstract

CTU Lecture am 8.3.2016: «Praktische Tipps und Hinweise zur Studienregistrierung»

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

07.03.16 - Sven Trelle, Kodirektor der CTU Bern, informiert Sie an der kommenden CTU Lecture über die wichtigsten Dos and Don'ts sowie die gesetzlichen Rahmenbedingungen, die Sie bei der Registrierung von klinischen Studien beachten sollten.

Die Folien zur Präsentation von Sven Trelle finden Sie hier.

Have your own Study Website

02.03.16 - The CTU Bern Data Management Team is offering a new service to support your study or project.

Whether to promote your study, to provide information to patients or to communicate with your sites, a website is a great tool to reach your target audiences. We can help you to establish your own project Website based on our pre-selected WordPress Templates with minimal costs. Feel free to contact us to discuss further about your future study/project website. For more information, click here.

Umfrage am Inselspital: Ihr Feedback zählt!

05.02.16 - Die CTU Bern ist bestrebt, den klinisch Forschenden am Inselspital bestmögliche Unterstützung bei Ihren Studienprojekten bieten zu können und das Dienstleistungsangebot entsprechend den Bedürfnissen weiter zu optimieren:
Durch die Umfrage wollen wir herausfinden, wie zufrieden Sie mit unseren Dienstleistungen und Mitarbeitenden sind und in welchen Bereichen wir uns weiter verbessern können, um die patientenorientierte klinische Forschung am Forschungsplatz Bern noch gezielter zu fördern.
Wir bitten Sie, sich 10 Minuten Zeit zu nehmen und an unserer Online-Befragung teilzunehmen: Hier geht's zur Umfrage.

CTU Lecture am 2.2.2016: «Forschungsverträge: Was gilt es zu beachten?»

unitectra
Technology Transfer
Universities of Basel, Bern and Zürich

27.01.16 - Dr. sc. nat. ETH Daniel Gisi, Technology Transfer Manager bei Unitectra, der Technologietransfer-Organisation der Universitäten Basel, Bern und Zürich stellt in seinem Referat Typen von Forschungsverträgen vor, die am Inselspital abgeschlossen werden und gibt wertvolle Tipps, worauf bei der Aushandlung von Verträgen geachtet werden muss.
In der anschliessenden Diskussion können Sie Ihre Fragen stellen und eigene Erfahrungen mit dem Experten und den anwesenden Kolleginnen und Kollegen austauschen.
Wir freuen uns auf Ihre Teilnahme!

Die Folien zur Präsentation von Herrn Dr. Gisi finden Sie hier.

Kantonale Ethikkommission Bern

CTU Lecture am 12.1.2016: «KEK Anträge: Wie reiche ich einen KEK Antrag korrekt ein? - Tipps und Tricks von der KEK Generalsekretärin»

05.01.2016 - Wir freuen uns, Ihnen das Referat von Frau Dr. sc. nat. Dorothy Pfiffner, Leiterin des Sekretariats der Kantonalen Ethikkommission Bern KEK, ankündigen zu dürfen: Am 12. Januar 2016 wird Frau Dr. Dorothy Pfiffner im Rahmen der CTU Lectures über häufige Rückstellungsgründe von Forschungsanträgen berichten sowie über die wichtigsten Anforderungen und Bedingungen der KEK referieren. Die CTU Lecture bietet Ihnen zudem die Gelegenheit, Fragen und Anliegen rund um das Thema Anträge der KEK direkt zu kommunizieren. Die Teilnahme ist kostenlos und ohne Voranmeldung möglich.

Weitere Informationen finden Sie hier.