bns
Benelux
Neuromodulation
Society

BNS NEWSLETTER

ISSUE NUMBER 3• JUNE 2023

PREFACE BY THE PRESIDENT

MAARTEN MOENS

Dear BNS-members,
Dear friends of Neuromodulation,

With the upcoming holidays, the BNS board is reaching out to all of our members with this third newsletter.

The organizing committee of e-INS in collaboration with the regional chapter presidents and the European director-at-large worked hard in front and behind the scenes in order to build a "super-edition" of the e-INS congress in Hamburg. In this edition, you will find more information about this event.

In this newsletter, we will also give you an updated overview of the existing national registries for neuromodulation in the BENELUX.

I wish you a refreshing summer break!

BNS
NEWSLETTER

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3RD JOINT CONGRESS OF THE INS EUROPEAN CHAPTERS

31 AUGUST – 02 SEPTEMBER, 2023 | HAMBURG, GERMANY

In Hamburg, the word for hello is *"moin"*

Prof. Dirk Rasche, MD, PhD

Prof. Jan Vesper, MD, PhD

Dear Colleagues,

Following Nijmegen in 2017 and Paris in 2021, we are eager to continue the successful tradition of meetings of the European chapters of the International Neuromodulation Society (INS) in Hamburg in 2023. It is therefore a great honour to invite you all to the 3rd Joint Congress of the INS European Chapters (e-INS 2023), which we will create together.

Please mark the days from 31 August to 2 September 2023 in your calendars!

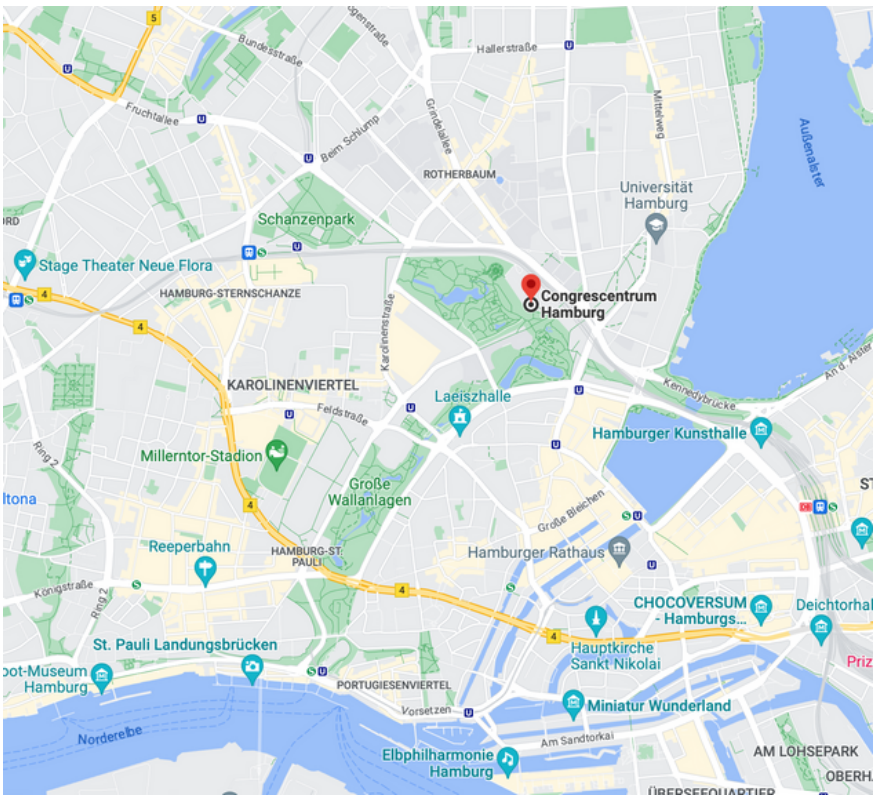
With the global pandemic always at the back of our minds, we fervently hope to meet face to face in one of Germany and Europe's up-and-coming metropolises. Hamburg, where the River Elbe flows into the North Sea, is Germany's second-largest city with a population of nearly two million. As a major port, Hamburg offers all the facets of a traditional and modern city. In addition to one of the world's largest transhipment ports for international maritime transport and the world-famous Reeperbahn, the Speicherstadt district in the port of Hamburg was declared a UNESCO World Heritage Site in 2015. Another must-see sight is the Elbphilharmonie. This is Hamburg's internationally renowned concert hall, which opened in 2017 and has since become an unofficial emblem of the city.

e-INS 2023 will be held at Congress Center Hamburg, which reopened in 2022 after extensive renovations and is thus an ideal conference venue.

The key topics will cover the entire neuromodulation spectrum and focus on the necessary network structures and future challenges. Together with European and international colleagues, we want to develop an attractive, modern and exciting scientific programme. We look forward to many fruitful discussions in Hamburg.

Kind regards,

CCH – Congress Center Hamburg
Congressplatz 1
20355 Hamburg



Workshop for Nurses and Allied Health Workers in Neuromodulation

After the success of the workshops in Nijmegen and Paris, we will once again be holding a workshop for nurses and allied health workers working in the field of neuromodulation, during the e-INS congress in Hamburg Germany.
The workshop will be organised by experienced nurses. It will cover a number of different topics and include an interactive program. Experiences will be shared and time in the program will be allocated for interesting and stimulating discussions and questions.
So let's come together. Take this opportunity to expand your network and collaborate with colleagues in Neuromodulation!!
Looking forward to seeing you at e-INS 2023,

Phyllis McPhillps and Caro Edelbroek

Preliminary program:

8:00	**Meet and Greet (Coffee and networking)**
8:30	**Welcome & Introduction** *Caro Edelbroek, The Netherlands & Phyllis McPhillips, Germany*
9:00	**The Future of SCS – Digital Remote, Artificial Intelligence, Tracking App, Smartwatches** *Andrea Dreyer, Germany; Ralph Aarsman, The Netherlands; Phyllis McPhillips, Germany*
10:00	**Coffee Break**
10:20	**Patient Education (Interactive activity)** *Colette Schultz, Germany*
10:50	**Case Report (Discussion) – The Role of the Nurse/ AHP** *Robin Wilding & Karla Toye, UK; Alba Maria Munoz, Spain*
11:30	**Coffee Break**
11:50	**Intrathecal Baclofen Pumps (Nursing report in-home care)** *Simone Goslinga-vam der Gaag, The Netherlands*
12:20	**Nurses in Research / Article discussion** *Caro Edelbroek, The Netherlands & Sylvie Crelerot France-Switzerland*
12:50	**Wrap Up** *Caro Edelbroek, The Netherlands & Phyllis McPhillips, Germany*

e-INS 2023 Cadaver Workshop

"Looking Over the Fence"

Cadaver Workshop Information

Date: Thursday, 31 August 2023
Time: 7:15 – 13:00
Location: TBD
Cost: 275 EUR
Discounted Price for INS members: 225 EUR

The e-INS cadaver workshop is a unique opportunity for experienced neuromodulators to learn and improve their knowledge and techniques from international experts in the field.

This workshop is aimed at experienced professionals who will be coached and mentored in advanced practices of neuromodulation. It will be both interesting and challenging, and participants will have gained important, relevant experience in neuromodulation by the end of the workshop.

Cadaver Topics:

- Spinal cord stimulation – Surgical
- Spinal cord stimulation – Percutaneous
- Dorsal root ganglion stimulation
- Sacral nerve stimulation
- Vagal nerve stimulation

reg_eins23@kenes.com to register for the cadaver workshop

For those who want to preview the scientific program of the e-INS congress:

SCAN ME

BNS chapter meeting & BNS member meeting at e-INS Hamburg

BNS MEMBERSHIP

The BNS Board encourages all members of the large neuromodulation family to get their BNS membership. Only by standing together, shoulder to shoulder, based on good practice and scientific sound evidence, new indications, new innovations and more awareness around neuromodulation will be achieved.
The BNS stands for being a trusty partner in the regulatory framework for the authorization and for increased focus on research with joint research projects and shared registries.

SCAN ME

New members may contact us at:
BNS.scientific@gmail.com or scan the QR code
170 euro/year

GOOD TO KNOW

Neuromodulation nurses, students and young researchers in neuromodulation can be a BNS member and therefore also an INS member for only 50 euro/year.

The BNS board believes that treating patients with neuromodulation is a multidisciplinary team effort and strongly encourages nurses and researchers to join the big BNS family!

Mail to: BNS.scientific@gmail.com or register yourself through the following link: https://cbd.eventsair.com/bns-ledenadministratie/bns

BNS MEMBERSHIP

WHAT IS IN FOR YOU?

- Acces to the journal 'Neuromodulation'
- Access to webinars & journal clubs
- Mentorship program
- Access to fact sheets and educational video's
- and so much more...

FUSS AFTER THE JAMA-PAPER

As discussed in the previous newsletter, Hara et al. published a devastating paper about SCS in JAMA in October 2022. The discussion of this paper read as follows:

"*Among patients with chronic radicular pain after lumbar spine surgery, spinal cord burst stimulation, compared with placebo stimulation, after placement of a spinal cord stimulator resulted in no significant difference in the change from baseline in self-reported back pain-related disability.*"

As a reaction, several key opinion leaders in the field of neuromodulation published their opinion regarding this manuscript. Sam Eldabe, Christopher Gilligan, Rod Taylor, Kiran Patel and Rui Duarte published an editoral in Pain Practice. The authors first applaud the study group in Norway for conducting a sham-controlled neuromodulation trial. Thereafter, concerns were discussed with respect to the study design, conduct and conclusions. The authors of the original paper replied to the audiance in an official response, published by JAMA. The stated concerns, with the provided answers are summarised below.

Concern: Radicular pain as target condition versus the often broader category of persistent spinal pain syndrome type 2.
Reply by Hara et Al.: Inclusion criteria were selected to maximize the likelihood of detecting a potential efficacy of burst SCS. The most important difference in the selection criteria for the study compared to daily clinical practice (according to the authors) is that patients with high doses of opioids, benzodiazepines, or both were excluded.

Concern: Oswestry Disability Index (ODI) are primary outcome variable (compared to normally used pain intensity scores) was not substantiated.
Reply by Hara et Al.: The ODI is the most validated primary endpoint in spine surgery trials. The large improvement in ODI score in the burst group is consistent with a meta-analysis. The improvement in ODI score in the placebo group was suprisingly (stated as such by the authors) as large.

Concern: Unusual SCS waveform
Reply by Hara et Al.: Stimulation settings were implemented as recommended by the manufacturer.

Concern: SCS trial criteria of at least 2 point reduction on NRS leg pain score (compared to the classical 50%).
Reply by Hara et Al.: The 2-point score on the NRS corresponds with the minimal clinically important difference for this questionnaire. Concerns regarding the cutoff value for pain reduction during the testing period were alleviated by the fact that the mean improvement was 63% (median, 5 points) in Numerical Rating Scale score for leg pain before entering the trial.

Concern: No possibility to ascertain how the participants remained blind to the intervention that they received. No formal assessment of blinding was performed for patients, nor for research team members.
Reply by Hara et Al.: Patients, surgeons, investigators and the statistician were blinded to treatment allocation during the entire study period. The treatment allocation guesses by patients were correct in 100 of 171 randomizations (58%), indicating successful blinding.

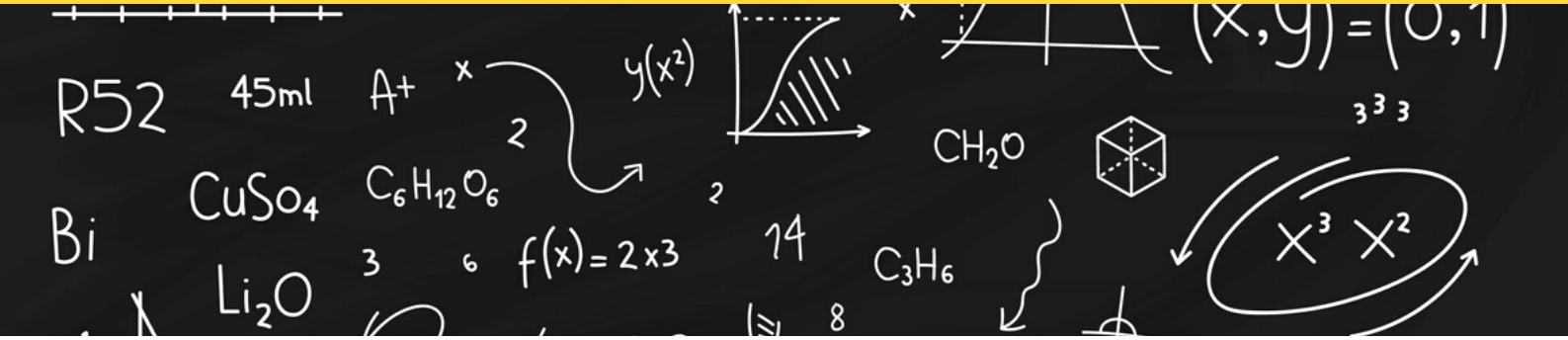
Alla Abd-Elsayed and Christopher Gilligan created an infographic to better denote the concerns with JAMA's Hara paper.

Despite the overwhelming amount of reactions on this paper, on June 13, 2023 the original authors published six-month follow-up results following the original RCT, again published in JAMA. Please find below the complete discussion section of this paper:

"*In this 6-month follow-up of a randomized trial on spinal cord burst stimulation for chronic radicular pain after lumbar spine surgery, the improvement in pain-related dis ability at posttrial follow-upwas not significantly different from placebo stimulation. This follow-up study does not support the use of spinal cord stimulation tomanage chronic radicular pain after spine surgery outside clinical trials. Limitations of the posttrial follow-up study included loss to follow-up, lack of de tails concerning the proportion of time spent using burst or tonic stimulation, and no self-reported outcome measures be yond pain-related disability.*"

Based on the continuing reactions on this paper, and the discussion that will be held at e-INS about this paper, we sincerely hope and are convinced that as a community, we can all stand together against the critisms about neuromodulation.

REGISTRIES IN THE BENELUX



REGISTRY OF NEUROMODULATION PATIENTS

THE NETHERLANDS

Within The Netherlands, the healtcare institute decided that since 2019, the following indications may apply for reimbursement: Persistent Spinal Pain Syndrome Type 2 (both previously denoted failed back and failed neck surgery syndrome patients), CRPS (including DRG for leg pain), diabetic polyneuropathy and small fiber polyneuropathy. As of today, indications that would benefit from this treatment such as angina, ischemic pain and peripheral nerve pain (important DRG indication) are not reimbursed and future studies are needed to obtain a reimbursement for these conditions.

In 2020, a mandatory registry was started. The operationalisation of mandatory means that all patients are included in the registry after intake until explantation. Patients implanted before 2020 are also incorporated in the registry. Patients that were implanted before 2020 with indication that have no reimbursement have leniency.

At the moment, discussions with the healthcare institute about other forms of polyneuropathy and the non surgical low back pain are ongoing. Since larger RCT's are up and running (4 RCT's for PSPS T1), it is expected that reimbursement will be a fact for these indications somewhere in the near future.

Since 2023 the registry is part of the DICA (Dutch institute of Cinical Audits), creating a strong basis to further develop the database, and creative scientific outcomes with this registry (the data are under ownership of the hospitals and the NVA 9 Dutch society of anesthesiologists).
An annual report is published every year containing pseudonymized data from all 26 centers. These centres work according to volume and quality criteria meaning that they have to implant at least 20 new patients or revisions per year. In case centers reach to the amount of 20 patients but not 50 patients, centers have to form a collaboration with another centers to create neuromodulation centers. In the system of the national registry, the collabarating centres are considered as 1 centre; at the moment we have 6 neuromodulation centres in The Netherlands. With the start of this registry , the old registry (which was not mandatory) stoppend and also the Dutch Society of Neuromodulation stopped as an organisation. It is important for Dutch implanters, nurses, specialized nurses and scientists to realize that the BNS is the only scientific society in the Netherlands to defend the Dutch neuromodulation interests . If you are not a member yet, please register, with the advantage that this is also a membership of the INS.

BELGIUM

In contrast with the situation in The Netherlands, the national Belgian registry was already mandatory since 1 January 2018. The Belgian registry, also called Neuro-Pain, is a web-based registry (https://www.neuro-pain.be), in which every new patient eligible for SCS and DRGs and replacements of electrodes and IPG's are registered. Reimbursement of the therapy (SCS and DRGs) is based on this registry.

Every patient in this register signed (digitally or via an uploaded form) an informed consent in which the patients commit themselves to be followed-up at least every 6 months in the hospital responsible for the treatment. The latter to discourage medical shopping.

The eligibility of every patient is well documented with clinical, physical and psychological parameters (by self-reported questionnaires) in combination with qualitative psychological assessments and outcomes of multidisciplinary meetings.

With this register, the trial period for both SCS and DRGs has been reduced from minimally 4 weeks to 3 weeks. During the trial period, a day-to-day diary measuring pain intensity, sleep quality and activity level is registered. Every week an MQS-III score is calculated from the remaining use of pain medication.
Besides the patient-oriented items, every specification of the implanted devices is also registered.

All these variables and assessments in this digital and GDPR compliant register are regulated by legislation and supervised by the Belgian Health Assurance. A dedicated digital health and med tech company provides the needed support.

In parallel to the registration of every patient by the local implanting centers, a national advisory board with representatives of scientific organizations concerning pain and neuromodulation, respresentatives of the national health assurance and services of public health assurance is assembled to give advice on specific indications, renewals of rechargeable IPG's implanted before 2018 and new therapies.

Recently, the first data extraction from this registry has been executed and analyzed. The publication of this data-extraction is expected in the fall of 2023.

The ultimate goal would be to create a global and uniform registry that is supported by the different INS chapters. This goal will still need a lot of preparatory work, however, the field is evolving towards this idea. Every European INS chapter and the European director-at-large are convinced and motivated to start up a European register for neuromodulation in the upcoming months.

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