

Opportunity for a Study Grant – a collaboration between Wellspect and the International Network of Spinal Cord Injury Nurses

Specialist spinal cord injury (SCI) nursing has a primary role in assisting patients with SCI to achieve and maintain the best possible level of physical and psychosocial well-being for the individual, the family and the society.

There is a range of therapies for managing bladder and bowel related problems in patients with SCI. Many intermittent catheter and transanal irrigation users will be introduced to the therapies and products by the SCI nurse. It is crucial for the patient's future acceptance and compliance, that the first experiences are as good as possible. Studies (e.g. clinical or education related studies) carried out by SCI nurses, with their perspectives on care, support and training, is very important for the development of best standards of clinical practice, and for securing a good start.

Wellspect launched LoFric® in 1983, and it was the first hydrophilic urinary catheter for intermittent catheterization. Navina Systems®, two different devices for transanal irrigation, was launched in 2016. Wellspect is committed to develop and manufacture products to improve the quality of life for patients who catheterize or use transanal irrigation, worldwide. The company's ambition is to work in close collaboration with both patients and clinical professionals to develop products.

Aim

With a Study Grant in collaboration with the International Network of SCI Nurses, Wellspect aims to encourage SCI nurses to perform studies within the areas of bladder catheterization and transanal irrigation. Wellspect believes that increased clinical evidence will expand nursing knowledge around bladder catheterization and transanal irrigation. Properly conducted studies, resulting in the publication of meaningful new data or documentation of clinical practice, will benefit both patients and health care professionals in the field.

Scope

The scope of this study grant is limited to studies related to bladder and bowel management/dysfunction in SCI individuals. The study may use qualitative (e.g. data collection through interviews) or quantitative (e.g. data collection through clinical examinations) methods. Any study design proposed will be considered.

Proposed areas for a study:

- General bladder catheterisation/transanal irrigation management in SCI
- Intermittent catheterization in SCI – Timing/Introduction/Follow-Up
- Bladder catheterisation management education – for patients or health care professionals
- Adherence and compliance to intermittent catheterization/transanal irrigation
- Intermittent catheterization/transanal irrigation and compliance to daily life
- Hand function and intermittent catheterization – training and product requirements
- Self-catheterization vs. assisted catheterization – impact on training and product choice
- Prevention of Urinary Tract Infections in SCI – focus on training and clinical practice

Application

Any member of the International SCI Nurse Network can apply for a Study Grant, using the template

in Appendix 1. The application must be submitted to Medical Affairs at WHC, MACE@wellspect.com no later than August 1st, 2020.

Selection

The applications will be reviewed by a committee consisting of the external experts Fiona Stephenson, FRCN, RN, UK and Debbie Green, RN, DMS, BA (Hons) UK and two delegates from Wellspect. The selected application will be announced at the International SCI Nurse Workshop in Yokohama, Japan in September 2020.

Agreement

The Study Grant is 2000€ and an agreement between the investigator (the applicant), the institution (e.g. clinic or university) and Wellspect must be set up. Half of the Study Grant support will be paid up front and a final payment will be processed upon delivery of the study results. In case you aim to perform a clinical study where human subjects are involved Wellspect will also contribute with the funding of a web-based ISO 14155 course. This course will support you in your work with the study, making you able to deliver high quality data. There is additional information regarding ISO 14155 in the next two sections.

ISO 14155

ISO 14155 is a guideline mandatory to be followed when performing clinical studies for medical devices (e.g. catheters and devices for transanal irrigation). The guideline addresses good clinical practice for the design, conduct, recording and reporting of clinical studies carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

ISO 14155 and Responsibilities

According to ISO 14155 a sponsor is defined as being an “individual or organization taking responsibility and liability for the initiation or implementation of a clinical investigation”. Furthermore, ISO 14155 states that “when an investigator initiates, implements and takes full responsibility for the clinical investigation, the investigator also assumes the role of the sponsor and is identified as the sponsor-investigator”. This investigator, or the investigator’s responsible medical institution, will act as the sponsor for the study and fulfill all the obligations of being a sponsor. The sponsor will make sure that the study is carried out in accordance with the protocol (detailed plan for the clinical study), ISO 14155, the regulations and guidelines governing medical practice, ethics and patient privacy in the countries where the study is carried out. The investigator will ensure that the study is approved by the institution’s relevant ethics committee and if appropriate by the relevant regulatory authorities. Wellspect will not have any sponsor responsibilities for the study.

Reporting

A report, in an optional format (such as Word, PDF, Excel, Powerpoint) shall be sent to MACE@wellspect.com when the study has been completed. An abstract submission must be sent to info@scinurse.org for the International Network of SCI Nurses Meeting, which will take place in conjunction with the ISCoS Annual Scientific Meeting 2020. If the abstract is approved for presentation, an application for a travel grant of 1500€ can be submitted to Wellspect. An acknowledgement informing that the study was supported by Wellspect shall be included in the manuscript.

Appendix 1. Application template

Protocol Synopsis Template

Date (YYYY-MM-DD)

Submitted by

Title and name of Investigator

Name of Institution

Address

Telephone number

E-mail address

Study title

Study design (*A one-sentence summary of study design features*)

Study centre(s) and number of subjects planned (*The address where the study will be conducted, number of patients planned and if applicable distribution of patients per site*)

Study period (*month & year*)

- **Estimated Start date** (*first patient enrolled*)
- **Estimated End date** (*last patient completed follow up*)
- **First data available for presentation**

Study objectives

Study population (*Short description of target population and indication studied, including relevant criteria for exclusion/inclusion, if applicable*)

Investigational product/comparator (*State the devices / products that will be investigated / used and for comparative studies also the comparator/s*)

Outcome variables

Materials and method

Statistical methods (*Describe where relevant the statistical methods to be used, the populations to be analysed (e.g. determination of sample size, intention to treat, per-protocol), and any interim analyses*)

Publications & Presentations (*Describe your plans with regard to publications or public presentations i.e. what journals or conferences/meetings*)