Timing of successful removal of urinary catheters in the neurosurgery intensive care unit

Submission date	Recruitment status	Prospectively registered
07/07/2023	No longer recruiting	[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
17/07/2023	Completed	[_] Results
Last Edited	Condition category	Individual participant data
17/07/2023	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

An indwelling urinary catheter (IDC) is a catheter which is inserted into the bladder through the urethra and remains in place to drain urine. The duration of indwelling urinary catheterization is a significant risk factor for developing urinary tract infections. Therefore, removing urinary catheters as soon as possible is recommended if there are no longer any indications for their use, such as ongoing urinary retention. This study aims to investigate whether the level of consciousness can be used as an indicator to determine the successful removal of urinary catheters in post-stroke patients admitted to the neurosurgical intensive care unit (NICU).

Who can participate? Patients in the NICU who have had a stroke and have urinary catheters (UCs)

What does the study involve?

The UC is removed early based on patient conditions. Successful removal of UCs is determined by the absence of the requirement for another UC to be inserted within 48 hours after UC removal.

What are the possible benefits and risks of participating? The benefits: prevention of urinary tract infections. The risk: unexpected urine retention which will be monitored and remedied right away.

Where is the study run from? Kaohsiung Veterans General Hospital (Taiwan)

When is the study starting and how long is it expected to run for? January 2013 to August 2018

Who is funding the study? Veterans Affairs Council (Taiwan) Who is the main contact? Dr Wei-Chuan Chen, coupe055@ms28.hinet.net

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers VGHKS16-CT7-08

Study information

Scientific Title

Does consciousness level determine the timing of successful removal of urinary catheters in the neurosurgery intensive care unit – implication to nosocomial infection prevention

Study objectives

The consciousness level can be an indicator in determining the successful removal of urinary catheters in post-stroke patients at the neurosurgical intensive care unit.

Ethics approval required Ethics approval required

Ethics approval(s)

Approved 03/01/2013, IRB of Kaohsiung Veterans General Hospital (No. 386. Da-chung 1st RD., Zuoying Dist., Kaohsiung, 813, Taiwan; +886 (0)73422121; info@vghks.org.tw), ref: VGHKS16-CT7-08

Study design

Quasi-experimental design trial

Primary study design Observational

Secondary study design Case series

Study setting(s) Hospital

Study type(s) Prevention, Safety

Participant information sheet Not applicable

Health condition(s) or problem(s) studied

Prevention of urinary tract infections in post-stroke patients with urinary catheters

Interventions

Early removal of urinary catheters to prevent urinary tract infections

The indications for the placement of urinary catheters (UCs) are as follows: (1) patients in critical condition with unstable hemodynamics; (2) postoperative monitoring of urine output; (3) specific surgical procedures requiring urinary catheterization (such as thoracic and pelvic surgery); (4) presence of an open wound around the sacral or perineal area; (5) acute urinary retention; and (6) reaching a consensus among hospice care providers to relieve discomfort through the use of indwelling urinary catheters. The decision to remove UCs was made by nursing-driven circle strategy (NDS) and bladder sonography scan protocol (BSP). NDS was determined through a collaborative effort of surgeons and nurses. On day five of UCs, the nurse leader and registered nurses would meet to discuss the removal timing, with a reminder provided by the ICU's information system (HIS). Following this discussion, the decision to remove the UCs was ultimately made by the surgeons.

Intervention Type

Other

Primary outcome measure

Successful removal of UCs, determined by the absence of the requirement for another UC to be inserted within 48 hours after the previous UC was removed. The timepoints are May 2014 - April 2016 (control) and May 2016 - August 2018 (testing)

Secondary outcome measures

1. Diabetes mellitus diagnosis based on standardized laboratory tests and patient records when the patients were admitted to hospital.

2. The incidence of catheter-associated urinary tract infections (CAUTIs), calculated according to the guidelines established by the Infectious Diseases Society of America (IDSA) and expressed as the number of CAUTI cases per 1,000 catheter days.

The timepoints are May 2014 - April 2016 (control) and May 2016 - August 2018 (testing)

Overall study start date

03/01/2013

Completion date 31/08/2018

Eligibility

Key inclusion criteria Post-stroke patients in the Neurosurgery Intensive Care Unit

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants 150

Total final enrolment 142

Key exclusion criteria

1. Patients who suffered from spinal diseases

2. History of prostate cancer or benign prostatic hyperplasia (BPH)

3. Participation refused by surgeons

Date of first enrolment 01/05/2014

Date of final enrolment 01/08/2018

Locations

Countries of recruitment Taiwan **Study participating centre Kaohsiung Veterans General Hospital** No.386, Da-chung 1st RD., Zuoying Dist. Kaohsiung Taiwan 813

Sponsor information

Organisation Veterans Affairs Council

Sponsor details

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Sponsor type Government

Website https://www.vac.gov.tw/mp-2.html

Funder(s)

Funder type Government

Funder Name Veterans Affairs Council

Results and Publications

Publication and dissemination plan Ready to submit to a high-impact peer-reviewed journal

Intention to publish date

31/07/2023

Individual participant data (IPD) sharing plan

The dataset is not expected to be made available because of the regulation of the Ministry of Health in Taiwan.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available