ISRCTN11643929 https://doi.org/10.1186/ISRCTN11643929

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

Submission date
07/07/2023

Recruitment status
No longer recruiting

Registration date
17/07/2023

Overall study status
Completed

Last Edited
17/07/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Contact name
Dr Wei-Chuan Chen

Contact details
No.386, Da-chung 1st. RD.
Zuoying Dist.
Kaohsiung
Taiwan
813
+886 (0)73422121
coupe055@ms28.hinet.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention, Safety

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(s)
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)

Key secondary outcome(s))
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)

Completion date
31/08/2018

Eligibility

Key inclusion criteria

Post-stroke patients in the Neurosurgery Intensive Care Unit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

Funder(s)

Funder type
Government

Funder Name
Veterans Affairs Council

Results and Publications

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