ISRCTN18989217 https://doi.org/10.1186/ISRCTN18989217

Long-term effects of a strategy to reduce inappropriate use of catheters

Submission date
07/02/2022

Recruitment status
No longer recruiting

Registration date
11/02/2022

Overall study status
Completed

Last Edited
08/11/2024

Condition category
Other

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

Plain English summary of protocol
Background and study aims
In the era of increasing healthcare costs, it is crucial to reduce low-value care with the aim of improving the quality and safety of care and lowering costs. One aspect of care that is routinely given but that may be necessary is the use of catheters.
A urinary catheter is a flexible tube used to empty the bladder and collect urine in a drainage bag.
A peripheral venous catheter is a catheter (small, flexible tube) placed into a peripheral vein for venous access to administer intravenous therapy such as medication fluids.
A multifaceted de-implementation strategy has proven to be effective in a trial called 'Reduce Inappropriate use of CATheters' (RICAT) in the Netherlands. However, knowledge about the sustainability of de-implementation strategies is lacking. The aim of this study is to investigate the long-term sustainability of the de-implementation strategy that was implemented three years ago during the RICAT-trial. Further, we aim to identify general factors that contribute to sustainable de-implementation through use of a qualitative interview study.

Who can participate?
Patients who are admitted to a medical, non-surgical, ward and who have a peripheral venous catheter (PVC) or urinary catheter on the days of data collection.

What does the study involve?
We will perform an observational quantitative study, in which we will prospectively include patients with a PVC or urinary catheter. For these patients, we will assess whether the medical indications for this catheter are appropriate on the days of data collection.

What are the possible benefits and risks of participating?
The results of this study will be used to further improve healthcare pathways regarding the appropriate use of catheters. The measurements do not influence patients' care and treatment plans. Further, the burden on patients is limited. A research physician will screen patients for having a PVC or urinary catheter, after which relevant data regarding the medical indication of the catheter will be collected from the electronic patient record.

Where is the study run from?
Amsterdam UMC, location AMC (the Netherlands)

When is the study starting and how long is it expected to run for?
November 2021 to April 2023

Who is funding the study?
ZonMw (the Netherlands)

Who is the main contact?
Tessa van Horrik, t.m.vanhorrik@amsterdamumc.nl
Dr Eva Verkerkeva.verkerk@radboudumc.nl

Contact information

Type(s)
Scientific

Contact name
Ms Tessa van Horrik

ORCID ID
http://orcid.org/0000-0002-3496-2203

Contact details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31(0)205665992
t.m.vanhorrik@amsterdamumc.nl

Type(s)
Scientific

Contact name
Dr Eva Verkerk

ORCID ID
http://orcid.org/0000-0002-6596-6207

Contact details
Kapittelweg 54
Nijmegen
Netherlands
6525 EP
+31(0)243616333
eva.verkerk@radboudumc.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Long-term sustainability of a de-implementation project to Reduce Inappropriate Use of CATheters

Acronym
RICAT-2

Study objectives
We hypothesized that we will measure a sustained reduction of inappropriate use of peripheral venous catheters (PVC) of 15%, similar to the results of the RICAT-trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
On 07/01/2022, the Medical Ethics Review Committee of the Academic Medical Center Amsterdam confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study and that official approval of this study by their committee is not required. Reference number W21_560#22.001

Study design
Mixed-methods design including an observational quantiative part and a qualitative interview study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
For the quantitative part, adult patients with a PVC or urinary catheter that are admitted to a medical ward. For the qualitative part, healthcare workers from the medical wards, who participated in executing and maintaining the de-implementation strategy.

Interventions
We will perform a multicenter observational study to measure the percentage of inappropriate use of peripheral intravenous catheters (PVCs) and urinary catheters. In addition, we will perform a qualitative interview study to assess to what extent the de-implementation strategy is maintained, and what barriers and facilitators apply to maintaining the effect of the de-implementation strategy.

Quantitative part: We will only collect data about the medical indication for the peripheral venous catheter or urinary catheter on the days of data collection.
Qualitative part: We will hold a one-time focus group interview with the healthcare workers in each participating hospital.

Intervention Type
Other

Primary outcome measure
Percentage of inappropriate use of PVCs on the days of data collection will be collected by a research physician or research student. These data will be collected from medical records in an electronic Good Clinical Practice-compliant database. Based on the information from the medical records, the research physician or research student will assess if the use is inappropriate. The following indications will be considered appropriate:
a. Peripheral intravenous catheter
• Delivery of peripherally compatible infusate (intravenous fluids and medications) at least once in 24 h
• Injection of contrast fluids
• Intravenous access for cardiac dysrhythmia
• Transfusion of blood and blood products
b. Urinary catheter
• Accurate measurements of urinary output in patients who are critically ill when required for treatment
• Acute urinary retention or bladder outlet obstruction (≥150 mL)
• Assist in healing of open sacral or perineal wounds in patients with urinary incontinence
• Continuous bladder irrigation for haematuria
• Palliative care for patients who are terminally ill if needed
• Patient requires prolonged immobilisation
• Before or after surgery according to (local) protocol
• Volume measurements of urine output for diagnostics (24 h urine), which cannot be assessed by other collection strategies

Secondary outcome measures
1. Number of patients with more than one PVC with an inappropriate indication on the days of data collection measured as above.
2. Barriers and facilitators of the sustainability of the effect of the de-implementation strategy

measured using the themes that will emerge from the results of the focus group interviews conducted at a single time point

Overall study start date
01/11/2021

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Adult patients admitted to internal medicine, gastroenterology, geriatric, oncology, and pulmonology wards, and non-surgical acute admission units who have a PVC or urinary catheter on the day of data collection, or
2. Healthcare workers (e.g., nurses, physicians) who are or who were responsible for maintaining the de-implementation strategy to reduce inappropriate use of catheters

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
1254 patients

Total final enrolment
1155

Key exclusion criteria
1. Patients who are admitted for an elective short stay, and patients who are terminally ill
2. Patients with chronic use of catheters, defined as having any type of catheter before hospital admission, and no new inserted catheter of any type

Date of first enrolment
01/05/2022

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC location AMC
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Study participating centre
Amsterdam UMC location Vumc
De Boelelaan 1117
Amsterdam
Netherlands
1081 HV

Study participating centre
BovenIJ ziekenhuis
Statenjachtstraat 1
Amsterdam
Netherlands
1034 CS

Study participating centre
Dijklander Ziekenhuis locatie Hoorn
Maelsonstraat 3
Hoorn
Netherlands
1624 NP

Study participating centre
Flevoziekenhuis
Hospitaalweg 1
Almere
Netherlands
1315 RA

Sponsor information

Organisation
Amsterdam University Medical Centers

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31(0)205669111
s.e.geerlings@amsterdamumc.nl

Sponsor type
Hospital/treatment centre

Website
https://www.amsterdamumc.org/research/institutes/cancer-center-amsterdam.htm

ROR
https://ror.org/05grdyy37

Organisation
Radboud University Nijmegen Medical Centre

Sponsor details
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6525 GA
+31(0)243611111
tijn.kool@radboudumc.nl

Sponsor type
Hospital/treatment centre

Website
https://www.radboudumc.nl/EN/Pages/default.aspx

Funder(s)

Funder type
Government

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
All relevant results of the study will be disseminated through publications in peer-reviewed journals and presentations at relevant –scientific- conferences. No identifiable patient data will be disseminated.

Intention to publish date
30/04/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/08/2024	08/11/2024	Yes	No