Title: Evaluate the Efficacy of Two Advanced Skin Treatment Regimens in Treating Incontinence-associated Dermatitis: Cluster Randomization Study

Study protocol

Study design

An open-label, cluster randomized, three-group, prospective study will be adopted. Cluster randomization will be used to allocate the selected wards to the experimental or control group for ease of operation (Hemming, Eldridge, Forbes, Weijer, amp; Taljaard, 2017), avoiding confusion on the treatment regimens and cross-contamination of subjects (Sedgwick, 2012). The randomized code for the nursing units will be generated using www.randomizer.org as Treatment 1 or Treatment 2 or Control. Blinding is not possible as the treatment products cannot be “masked”. A purposive sampling on inpatients with IAD will be recruited into the study upon consent. The inclusion and exclusion criteria are as listed in K1 amp; K2. The participants will automatically follow the randomization code selected (implied either control or treatment arm) by the nursing unit he is being admitted.

Study materials

Control

The control regimen for IAD is the current standard of care implemented by the organizations participating in the study. The control regime are combination of treatment - varied practices currently for the treatment of IAD – including the use of potassium permanganate, barrier cream or zinc oxide with skin wipes or soap and water for cleaning

Treatment products

The recommended treatment for IAD should include a structured skin care regimen containing a skin cleanser and a skin protectant. The chemical components recommended as protectants should contain either zinc-based, petrolatum-based, dimenthicone-based, or an acrylic polymer. The four preselected products for review are: (1) Conveen easi cleanse and Coloplast Conveen critic barrier (2) 3M No rinse cleanser and 3M Cavilon No string Barrier Film (3) 3M No rinse cleaner and 3M Cavilon Advanced Skin Protectant(4) Smith and Nephew Moisturizing cleanser and Secura EP cream 30%

Study process

Screening/Recruitment

1. When a potential candidate is identified, the research team members will be activated.

2. Eligible participants from the cluster randomized nursing units will be screened. If they meet the inclusion/exclusion criteria, the PI / co-I will be approached the participants face-to-face.

3. The study information will be explained to them at their individual bedside cubicles or a quiet corner of the nursing unit for semi-ambulant participants. Time will be given for consideration to the study. All questions asked
will be answered. Upon verbal agreement, the consent will be taken using the appropriate ICFs attached.

4. The nurse-in-charge/doctor-in-charge of the patient will be notified of the participant's agreement to the study.

Study day process

5. Arrangement will be made with the nurse-in-charge to synchronize the daily skin assessments with the study assessment to avoid unnecessary exposure.

6. An initial baseline assessment (Day 0) will be conduct on the participant's buttocks, posterior aspect of thigh and perineal region. The subject will be placed on a lateral comfortable position.

7. Observations made will include the amount and extent of denudement, exudate level, redness, signs of infection and the skin condition.

8. A baseline photo will be taken prior treatment.

9. Concealed treatment codes placed in a sealed opaque envelope will be used for randomizing the cluster. Each nursing units will be asked to draw the sealed envelope. With the sealed envelopes contained numbers 1 to 3 where 1 = Standard of care (control), 2 = Treatment regimen 1, 3 = Treatment regime 2. Each draw will determine the allotted treatment for the study site to adopt.

10. The treatment products will be issued to the nurse for application.

11. The treatment regimens will be applied as per manufacturer's recommendation.

12. Patients will be followed up three times a week for a maximum of 21 days, or until the IAD has healed or discharged from the study site.

13. Each review (including baseline assessment), photos will be taken to document the extent of the IAD over the buttocks and/or thighs and/ or perineal region.

14. All assessments will be made using IADS-D and GLOBIAD tool. Permissions to use the assessment tool has been given.

15. On Day 3, 5 and 7, an assessment will be made to the skin appearance if the IAD has not resolved.

16. Patients on treatment regimens will be identified using visual cue - different flower icons. Patients on control regimens will be treated as per hospital policy on data management

17. All collected data will be entered into the CRF.

18. Upon completion of the data collection, the data will be transcribed into EXCEL and validated independently by two different assigned persons.

19. The validated data in EXCEL will be imported into SPSS and R for data analysis on a later date.

Data collection

Baseline parameters and other outcome measures that will be collected include the pain scores, classification of IAD and healing rates, episodes of incontinence, deterioration to PI or development of other adverse events (Kon et al., 2017) will be collected based on the case record form. Subsequently, 4 more assessments will be made on the participants on the progress of the IAD following treatment(s)/control regimens.

Data Analysis plan

All data will be entered into a Microsoft Office Excel 2013 and independently verified for accuracy of the transcription. The data will then be imported into Statistical Package for the Social Sciences (SPSS) IBM Version 24 and R for analysis and coding. Descriptive analysis including means and standard deviations or medians and interquartile ranges for the numerical variables and frequencies for categorical variables will be used to describe the study sample characteristics. ANOVA will be used to analyse for group differences. The measure of effect (risk difference or mean difference) and a confidence interval or measure of variation will be examined. The intra-cluster correlation coefficient (ICC) will be examined with an ICC of 0.10 used as the acceptable determine for cluster independence during observations (Thomson 2012). Multivariate regression will be used to evaluate the effect of treatment regimens, adjusting for risk factors. A significance level of 0.05 will be used.

We will measure skin characteristics by an independent wound nurse clinician to determine if the photographs reflected any change in skin, size of redness, skin infection or other changes during the follow-up of days 1, 3, 5 and 7 after application of the product. Photographs will be examined to detect any signs of improvement or deterioration in skin condition – redness, maceration of skin and skin erosion (Van de Bussche et al., 2018). A copy of the photograph assessment form is attached. The outcome measures include the pain scores, assessment scores for IAD and healing rates, episodes of incontinence, deterioration to PI or development of other adverse events (Kon et al., 2017).