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To compare the polyurethane foam dressing (hydrocellular) and the hydrocolloid dressing in patients with Pressure Ulcers (stage II) in primary care

Submission date
19/06/2012

Recruitment status
No longer recruiting

Registration date
19/07/2012

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pressure ulcers are wounds in the skin and underlying tissues that are caused by continuous pressure or friction between an external surface and a bone or cartilage surface. They can lead to complications such as infections, reduce the patient's quality of life and are estimated to cost 5% of the annual health expenses in Spain. Specially designed dressings and bandages can be used to protect pressure ulcers and speed up the healing process. The aim of this study is to assess the effectiveness of two dressings, a polyurethane foam dressing and a hydrocolloid dressing, for the treatment of pressure ulcers.

Who can participate?
Patients aged 18 and over with at least one pressure ulcer

What does the study involve?
Participants are randomly allocated to be treated with either a polyurethane foam dressing or a hydrocolloid dressing. All participants also receive the standard healing procedures and prevention activities, such as regularly changing their position and using pressure-relieving support surfaces such as mattresses and cushions. Healing of the pressure ulcer is assessed by measuring the wound size after 8 weeks. The cost-effectiveness, side effects and convenience of using the dressings are also assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Primary Health Service of the Balearic Islands (Spain)

When is the study starting and how long is it expected to run for?
September 2012 to September 2015

Who is funding the study?
Directorate General for Evaluation and Research Promotion, Carlos III Institute of Health (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2012-003945-14

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI11-01674

Study information

Scientific Title
A multicenter, randomized, single-blind clinical trial to compare the polyurethane foam dressing (hydrocellular) and the hydrocolloid dressing in patients with Pressure Ulcers (stage II) in primary care

Acronym
PrU-II

Study objectives
The proportion of stage II ulcers healed after 8 weeks through hydrocellular dressings is not higher than the 10% of the proportion of ulcers healed through hydrocolloid dressings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Balearic Islands (Mallorca-Illes Balears)

Study design
Multicenter open-label randomized clinical trial of two parallel treatment arms

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Stage II pressure ulcer (ulcer with epithelialisation tissue)

Interventions
Patients will be randomized using a unic randomisation list obtained by an informatic programme. Each participant center (Primary health center/nursing home) will be provided from this list.

Treatment 1: polyuretane foam dressing
Treatment 2: hydrocolloid dressing

Each patient has the same probability in being cured by polyurethane foam dressing or hydrocolloid one. In addition, an Investigator's Brochure will explain how to proceed to cure ulcer in order to standardize the process and reduce bias.

If patient is attended at home, he or she or their relatives will be provided with a "patient's diary" where they should note down how often they change position or if they use pressure-relieving surfaces. The position changes are based on the local Good Clinical Practice Guideline elaborated by the Advisory Panel of Pressure Ulcers from Mallorca. This process also has been standardized to reduce bias.

If patient is admitted in a home-nursing, leader nurse should note down all this information on nursing records.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Stage II PrU healing (ulcer with epithelialisation tissue). Wound size in cm2, exudate and type of tissue through the Pressure Ulcer Healing Chart (PUSH) assessment tool. This information would be weekly collected until the end of the study or until healing of stage II PrU. Moreover, PrU would be stratified depending on the classification established by the European Ulcer Advisory Panel (EPUAP).

Secondary outcome measures
1. Cost-efficacy outcomes:The costs in the proportion of healed ulcers and the costs per treated patient would be calculated to estimate the cost-effectiveness. In order to do this estimation, information relating to direct costs would be collected, implying number of used dressings, frequency in the changing of dressings, use of secondary dressings and time spent in the healing process. Furthermore, the costs due to the evolution of stage II PrU into a higher level, infection or necrosis, days of hospitalisation, additional treatment and treatment of adverse events or complications would also be taken into account. Indirect costs would not be considered.
2. Assessment of safety aspects. Outcomes related to the detection of adverse events, complications in the ulcer and infection.
3. Assessment of convenience of dressings of study. Information relating to the following outcomes and regarding the person who is involved in the process of healing and the one who is receiving it (treatment of the PrU): adherence, management of the dressing, (ease of removal of the dressing), comfort of the patient, pain of the patient during process of healing of stage II PrU and time spent in the stage II PrU process of healing.

Overall study start date
30/09/2012

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Patients ≥ 18 years old with pressure ulcers (PrU) at stage II diagnostic (*In the case that a patient has more than one stage II PrU, only the ulcer with the largest surface area would be taken into account. This decision does not imply the stopping of normal treatment for the rest of the ulcers, and neither does stop the prevention of the pressure)
2. Patients attended in Primary Care in domiciliary care with stage II PrU
3. Patients in nursery homes with stage II PrU

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
820 patients

Key exclusion criteria
1. Patients with a diagnostic of PrU I, III or IV
2. Patients with non classifiable PrU
3. Hospitalised patients with any stage PrU (including stage II ones)
4. Patients with previous surgical treatment of the PrU and/or patients with previously irradiated PrU areas
5. Patients who have taken part in another clinical research study in the previous 3 months
6. Patients with allergy or hypersensitivity to the materials of the dressings
7. Patients with PrU who show signs of basal infection (sepsis/bacterial), cellulitis or osteomyelitis
8. Patients with venous ulcers and/or diabetic foot.
9. Patients in extreme gravity and/or terminal situation with < 3 points in the Braden Scale and /or a life expectancy of less than 1 month
10. Type I diabetic patients

Date of first enrolment
30/09/2012

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Spain

Study participating centre
C/Terral 37B
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Sponsor information

Organisation
Primary Health Service of the Balearic Islands (Spain)

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Sponsor type
Not defined

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Government

Funder Name
Directorate General for Evaluation and Research Promotion, Carlos III Institute of Health (Spain) ref: PI11/01674

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/12/2013		Yes	No