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100 Patient study of PICO v Standard care in chronic / sub-acute wounds

Submission date	Recruitment status	[X] Prospectively registered
28/09/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/11/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/04/2019	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The main aim of the study is to compare a dressing with negative pressure with a range of dressings without negative pressure and assess if there is any difference in how long it takes to heal various types of wounds. A dressing with negative pressure creates a vacuum which is going to help healing the wound. The study will check if there are differences in the wound size, appearance of the skin surrounding wounds, infections, pain, wound recurrence and cost associated with the dressings. The study will also explore the patients experiences and views on being treated with PICO (a brand of dressing with negative pressure).

Who can participate?
Males and females, English speaking over 18 years of age who have a wound (present for less than 1 year) being managed in a community setting can take part.

What does the study involve?
You will be randomly allocated to receive either PICO (negative pressure dressing) or continue to receive standard dressings for your wound over a 12 week period. All your dressing changes will take place whenever is appropriate to change the dressing and this will be done by the nurse or doctor in the study. This can be at the GP centre or clinic or at home if necessary. There will be an initial assessment of your wound by the doctor or nurse treating you and two questionnaires will be asked and completed by the nurse or doctor treating you. There will be a wound assessment each week which should take place at one of your dressing changes. Your wound will be photographed each week and traced with a sterile film so we can calculate the size of the wound. If your wound heals during the study you will be asked to complete a questionnaire and to come back for a last assessment when your week 12 assessment would have taken place. Two questionnaires will be asked and completed by the nurse or doctor treating you at the end of the 12 weeks. Those patients being treated with PICO will have one interview during the study with a researcher who will ask questions related to how you have found this treatment.

What are the possible benefits and risks of participating?
There are no risks or benefits to taking part in the study, all products are commercially available products that are in use for the wounds included in the study. The only side effect of PICO is pain in some patients when the negative pressure dressing initially is switched on.

Where is the study run from?
There are approximately 20 centres taking part in the study across England (UK)

When is the study starting and how long is it expected to run for?
November 2011 to August 2012

Who is funding the study?
Smith & Nephew Medical Ltd (UK)

Who is the main contact?
Professor Christine Moffatt

Contact information

Type(s)
Scientific

Contact name
Prof Christine Moffatt

Contact details
The Royal Derby Hospital
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Derby
United Kingdom
DE22 3NE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02458859

Secondary identifying numbers
CE/044/PIC

Study information

Scientific Title
A 100 patient, prospective, randomised, clinical evaluation comparing clinical and health economic outcomes between patients with chronic or sub-acute wounds treated with either PICO or standard care dressings and a qualitative study to explore the experiences of patients receiving PICO with particular emphasis on concordance

Study objectives

To assess if there is a difference in time to wound closure (healing) for chronic and sub-acute wounds between patients treated with PICO or standard care

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East Northern and Yorkshire

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic and sub acute wounds

Interventions
PICO treatment group patients will be treated with PICO for up to 12 weeks with a wound assessment conducted weekly up to week 12.

Standard care group patients will be treated with appropriate standard care from the centre formulary for up to 12 weeks and a wound assessment is conducted weekly up to week 12.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time to wound closure as assessed by the clinician

Secondary outcome measures

1. Wound closure and wound progress
1.1. Area
1.2. Depth
1.3. Volume
1.4. Granulation tissue and healthy tissue
1.5. Condition of the surrounding skin
2. Wound recurrence
2.1. Infection
2.2. Clinical signs of Infection
2.3. Pain
2.4. Exudate
3. Health Economics
4. Materials
4.1. The number of dressings applied
4.2. Additional materials used
5. Cost of materials
5.1. Cost of dressings applied per dressing change
5.2. Cost of additional materials used
5.3. Total cost of materials used per dressing change
5.4. Cost of dressings applied during treatment
5.5. Cost of additional materials used to secure foam and organ protection layer during treatment
5.6. Total cost of materials used during treatment
5.7. Total Materials cost per week
6. Personnel
7. Additional interventions
8. Total costs
9. Health state
10. Cardiff Wound Impact Schedule
11. Quality adjusted life year

Overall study start date
25/11/2011

Completion date
25/08/2012

Eligibility

Key inclusion criteria
1. Patients >18 years old
2. Males and females. If female, they must not be pregnant or lactating. If female and of reproductive age, a pregnancy test will be provided.
3. The patient or their legal representative (if the patient is incapable of giving legal consent), is able to understand the trial and is willing to consent to the trial
4. Patients with sub-acute or chronic wounds (diabetic foot ulcer, pressure ulcer, venous leg ulcer, or other chronic) suitable for treatment with a PICO dressing
5. Wound duration less than or equal to 52 weeks

6. Wound area range more than or equal to 5 cm2 at start of screening period
7. Wound maximum linear dimension less than or equal to 15cm
8. Able to use English for the interview

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients with known allergies to product components (silicone adhesives and polyurethane films (direct contact with wound), acrylic adhesives (direct contact with skin), polyethylene fabrics and super-absorbent powders (polyacrylates) (within the dressing)
2. Wounds which have an infection which is not being treated with systemic antibiotics
3. Wounds which are actively bleeding
4. Exposure of blood vessels, organs, bone or tendon at the base of the reference wound
5. Exclude undermining or tunnelling present or suspected in the wound
6. Use of negative pressure device on wound in the last 30 days
7. Malignant wounds / malignancy in the wound
8. Systemic infection not being treated with systemic antibiotics
9. Simultaneous treatment with other experimental wound care procedures or devices
10. Patients with a known history of poor compliance with medical treatment
11. Patients who have participated in this trial previously and who closed or were withdrawn
12. Patients who are unable to understand the aims and objectives of the trial

Date of first enrolment
25/11/2011

Date of final enrolment
25/08/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

The Royal Derby Hospital
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Smith & Nephew Medical Ltd

Sponsor details
101 Hesse Road
Hull
United Kingdom
HU3 2BN

Sponsor type
Industry

Website
http://global.smith-nephew.com/

ROR
https://ror.org/03agge938

Funder(s)

Funder type
Industry

Funder Name
Smith & Nephew Medical Ltd (UK)

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