A randomised clinical trial comparing hydrocolloid, phenytoin and simple dressing in the treatment of pressure ulcer

Submission date	Recruitment status	Prospectively registered
10/10/2004	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
18/10/2004	Completed	[X] Results
Last Edited 23/01/2020	Condition category Skin and Connective Tissue Diseases	[] Individual participant data
Z3/U1/ZUZU	2011 9110 COHIECTIVE H220E D12E92E2	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number 258147739

Study information

Scientific Title

A randomised clinical trial comparing hydrocolloid, phenytoin and simple dressing in the treatment of pressure ulcer

Acronym

SCI-HD-PC-SD

Study objectives

Added 19/08/09:

In Iran, 5000 patients suffer from spinal cord injury (SCI): of these, 2000 are Iran-Iraq war victims and 3000 were handicapped by other causes. In view of the enormous prevalence of pressure ulcers in war victims and other spinal handicap patients, and the importance of these lesions in terms of morbidity, mortality and cost of treatment, we have compared the efficacies of applying hydrocolloid dressing, phenytoin cream and a simple dressing. The aims were to determine: 1. which is the most effective in terms of complete ulcer healing; 2. whether healing rates differ with respect to the ulcer stage (I and II) or location (gluteal, ischial, sacral) using these three different methods.

As of 19/08/09 this record has been extensively updated. All updates can be found under the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised single blind active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pressure ulcer

Interventions

Three therapeutic methods:

- 1. Simple dressing
- 2. Hydrocolloid dressing
- 3. Phenytoin cream

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. Ulcer healing
- 1.1 Complete ulcer healing, defined as:
- 1.1.1. For stage I ulcer, intact epidermis, no red area
- 1.1.2. For stage II ulcers, intact dermis and epidermis, no abrasion or ulceration.
- 1.2. Partial healing, defined as any decrease in ulcer size compared to the baseline ulcer tracing, excluding complete healing
- 1.3. Without improvement, defined as no change in ulcer size compared to the baseline ulcer tracing
- 1.4. Worsening, defined as any increase in ulcer size compared to the baseline ulcer tracing.
- 2. Response rate

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/05/2002

Eligibility

Key inclusion criteria

Current information as of 19/08/09:

- 1. Paraplegia caused by spinal cord injury
- 2. Pressure ulcer stage I and II according to Shea classification or National Pressure Ulcer Advisory Panel
- 3. Patient's informed consent
- 4. Smoothness of ulcer area to establish whether adhesive could be used at the site

Initial information at time of registration:

83 spinal cord victims of IRAN-IRAQ with pressure ulcer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Added 19/08/09:

- 1. Addiction
- 2. Heavy smoking (more than 20 cigarettes a day or more than 10 packs per year
- 3. Concomitant chronic disease (e.g. diabetes mellitus or frank vascular disease such as Buerger's disease)

Date of first enrolment

01/03/2002

Date of final enrolment

01/05/2002

Locations

Countries of recruitment

Iran

Iraq

Study participating centre

No. 99 Tehran Iran 1415994978

Sponsor information

Organisation

Janbazan Medical and Engineering Research Centre (JMERC)

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults15/12/2004YesNo