

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

Submission date 10/10/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 18/10/2004	Overall study status Completed	☐ Protocol
Last Edited 23/01/2020	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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

Primary study design

Interventional

Study design

Randomised single blind active controlled parallel group trial

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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/12/2004		Yes	No