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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	**Condition category**	[_] Individual participant data
23/01/2020	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2002

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

Age group
Adult

Sex
Male

Target number of participants
83

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
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Sponsor information

Organisation
Janbazan Medical and Engineering Research Centre (JMERC)

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Sponsor type
Research organisation

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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?
Results article	results	15/12/2004		Yes	No