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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
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

#### Contact name

Prof Hossein Khedmat

#### Contact details

No. 99
Physicians Building
Rooyan Alley
Next to Sassan Hospital
Keshavarz BLVD
Tehran
Iran
1415994978
+98 (0)21 8964763
h\_khedmat@hotmail.com

# 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 1415994978

# Sponsor information

#### Organisation

Janbazan Medical and Engineering Research Centre (JMERC)

#### Sponsor details

No. 25 Farrokh Alley Moghadas Ardabili. St Tehran Iran 19615/616 +98 (0)21 2412114 info@jmerc.ac.ir

## 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