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Comparing oil based ointment versus standard practice for the treatment of moderate burns in Greece: A cost effectiveness evaluation

Submission date
23/10/2010

Recruitment status
No longer recruiting

Registration date
12/11/2010

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Moist exposed burn ointment versus povidone iodine plus bepanthenol for patients with moderate burns (TBSA<15%)

Study objectives
Moist exposed burn ointment (MEBO) substantially reduces the time of wound healing.

Further reading:
http://www.ncbi.nlm.nih.gov/pubmed/20121563

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific Committee of General Regional Hospital of Athens, Dr. Georgios Papastratis approved on the 1st of February 200 (ref: 199/2000)

Study design
Prospective pragmatic randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Prof V. Carayanni [bilma@otenet.gr] to request a patient information sheet

Health condition(s) or problem(s) studied
Burns

Interventions
Patients will be randomised to receive either:
1. Moist exposed burn ointment (MEBO), applied twice per day with the assistance of nursing staff
2. Povidone iodine plus bepanthenol. Bepanthenol cream is self applied or applied with the assistance of nursing personnel twice per day after the third or fourth day of therapy with povidone iodine according to the degree of repithelilization.
The burn wounds (both groups) were also treated and lightly debrided by antiseptic in the shower every second day by nursing or medical personnel. Also, dressing of the burn wounds

during hospitalization is not applicable primarily because of considerable shortcomings in nursing personnel.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
1. Mean reduction in days of in-hospital stay for patients in both groups (standard length of stay according to the experts=10 days)
2. Time of recovery for patients with superficial partial thickness burns (Transepidermal Water Loss [TEWL] <60 gr/m2/h) using the TEWL indicator, recovery defined as 50% reduction of the TEWL on the first day

Secondary outcome measures
1. Pain
A visual analogue scale of 1 to 10 is used for pain measurement (0 = no pain; 1-2 = slight pain; 3-4 = mild pain; 5 = moderate pain; 6-9 = moderately severe pain; 10 = severe pain). Pain scores were recorded twice daily by the doctors. Pain medication is given upon patient demand
2. Clinical evaluation of the appearance of burn limits
A clinical evaluation of the appearance of burn limits is made each day by the doctor. We have used a binary and a continuous variable to quantify these criteria. The modalities of the first variable are:
2.1. Healthy appearance of burn limits
2.2. No Healthy appearance (presenting redness, swelling, other)

Overall study start date
05/01/2002

Completion date
05/01/2006

Eligibility

Key inclusion criteria
1. Total Burns Surface Area (TBSA) <15%.
2. Thermal burns
3. No need of surgical operation
4. Either sex, aged 18-75

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
214

Total final enrolment
211

Key exclusion criteria
Systematic diseases (cancer and diabetes)

Date of first enrolment
05/01/2002

Date of final enrolment
05/01/2006

Locations

Countries of recruitment
Greece

Study participating centre
Department of Plastic Surgery, Microsurgery and Burn Center, General State Hospital of Athens G. Gennimatas, 154 Mesogion Avenue Greece
Athens
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11141

Sponsor information

Organisation
Regional General Hospital of Athens Georgios Gennimatas (Greece)

Sponsor details
c/o I. Ioannovits
Department of Plastic Surgery
Microsurgery and Burn Center
154 Mesogion Avenue Greece

Athens
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11141

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00zq17821

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Regional General Hospital of Athens Georgios Gennimatas (Greece) - Department of Plastic Surgery, Microsurgery and Burn Center (equipment, stock medicines [except MEBO], and personnel

Funder Name
MEBO International Group Company (MEBO medicines) (China)

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	01/12/2011	18/12/2020	Yes	No