

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

☐ Prospectively registered

☐ Protocol

Registration date

12/11/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/12/2020

Condition category

Injury, Occupational Diseases, Poisoning

☐ 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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Contact details

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Additional identifiers

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)

Primary study design

Interventional

Study design

Prospective pragmatic randomised trial

Study type(s)

Treatment

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 bepantenol. Bepantenol 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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

All

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

Greece

11141

Sponsor information

Organisation

Regional General Hospital of Athens Georgios Gennimatas (Greece)

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

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