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Efficacy of a natural polymer solution product for the prevention of wet gangrene

Submission date
31/01/2012

Recruitment status
No longer recruiting

Registration date
14/02/2012

Overall study status
Completed

Last Edited
28/07/2014

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Gangrene is a serious condition in which a loss of blood supply causes body tissue to die. It can affect any part of the body but typically starts in the toes, feet, fingers and hands. The management of gangrene differs according to whether it is sterile/aseptic (dry) or infected /septic (wet). In most cases, aseptic dry gangrenous tissue is left to spontaneously detach (auto-amputation). Surgical removal of dead tissues and amputation are usually reserved for infected or septic wet gangrene. However, dry gangrene can develop into wet gangrene, often as a result of infection in immune-compromised patients with diabetes. Therefore, every effort must be made to prevent infection of dry gangrenous tissue. Elderly, bed-ridden patients with several serious illnesses and patients with a short life expectancy, particularly those in intensive care units, may also require conservative, non-surgical interventions. Moreover, patients may refuse amputations for religious reasons. Some patients are temporarily unable to undergo any surgical intervention, including major amputations. In these cases, the attending physicians must endeavor to prevent the transformation of dry to wet gangrene, while waiting for improvements in the patients condition.
In this study we aim to test whether embalming dead parts with a natural polymer solution, Shellac, could preserve dry gangrenous tissues in diabetic patients and prevent infection. Shellac is natural polymer of animal origin derived from the hardened secretion of the lac insect. Shellac solution was already used successfully by our group in embalming cadavers and it is patented for the treatment of gangrene. It was also tested microbiologically and found to be sterile. The early results of using Shellac as a non-toxic preservative for human embalming were promising. Our aim is to compare the outcomes of Shellac compared with standard treatment (povidone-iodine [PVP-I]] administered to prevent the progression of dry gangrene to wet gangrene, and prevent extension of gangrene to adjacent healthy tissues in patients with diabetes who were given the option of waiting for auto-amputation.

Who can participate?
Patients with diabetes with peripheral dry well-demarcated gangrene in their feet who were offered the option to wait for non-surgical auto-amputation, and geriatric bed-ridden patients with diabetes who refused amputation and/or were contra-indicated for re-vascularization or surgery.

What does the study involve?
Patients will be randomly allocated to receive either topical application of PVP-I (conventional treatment) or Shellac solution to the gangrenous areas. Shellac will be applied by soaking sterile gauze in Shellac solution for 30 seconds, which will then be used to swab the gangrenous tissue. The tissue was then left to dry for about 5 min. An alcohol swab will be used to clean the Shellac from the healthy tissue adjacent to the gangrenous tissue. A light dry dressing will be applied 10 minutes later and left undisturbed for 24 hours. After 24 hours, the dressing will then be removed and the gangrenous area will be swabbed again with ethanol to remove the Shellac. In the conventional treatment group, the same steps will be applied, but the gauze will be soaked in PVP-I instead of Shellac. The procedure will be repeated once daily in the conventional treatment group and when needed, such as after showering or removal of dressing in the Shellac group. All patients will be asked to visit the clinic every month or when signs of inflammation or fever were observed. Patients who show progression of gangrene or evidence of infection will exit the study.

What are the possible benefits and risks of participating?
There are no known risks to participants.

Where is the study run from?
The study takes place at the multi-disciplinary diabetic foot research clinic at King Abdulaziz University Hospital, Jeddah, Saudi Arabia.

When is study starting and how long is it expected to run for?
Patients will be enrolled in the study between January 2010 and December 2010. Follow-up examinations will continue until July 2011.

Who is funding the study?
Mohammad Hussein Al-Amoudi Scientific Chair for Diabetic Foot Research.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of 'Shellac', a natural polymer product, for the prevention of wet gangrene: a pilot randomized controlled trial

Study objectives
We will test whether embalming with a natural polymer solution, 'Shellac', could preserve dry gangrenous tissues in diabetic patients and prevent infection/sepsis.

We hypothesized that this approach would reduce the amputation rate in patients with un-reconstructable peripheral arterial disease (PAD), in patients who:
1. Refused amputation for cultural reasons
2. Were unsuitable for immediate amputation and/or were waiting for improvements in their condition to undergo re-vascularization
3. Were geriatric, bed-ridden patients with a short life expectancy contra-indicated for surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
King Abdulaziz University Bioethical Research Committee, 29/06/2009, ref: 299-09

Study design
Single-center randomized controlled 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 use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetic complications, gangrene, atheroschlerosis, peripheral arterial disease

Interventions
Patients were allocated to receive either topical application of PVP-I (conventional treatment) or 'Shellac' solution to the necrotic areas.

Shellac was applied by soaking a 4 × 4 cm sterile gauze in Shellac solution for 30 seconds, which was then used to swab the gangrenous tissue. The tissue was then left to dry for approximately 5 min. An alcohol swab was used to clean the Shellac from the healthy tissue adjacent to the gangrenous tissue. A light dry dressing was applied 10 min later and left undisturbed for 24 hours. After 24 hours, the dressing was removed and the gangrenous area was swabbed again with ethanol to remove the Shellac. The Shellac was re-applied again 5 min later.

In the conventional treatment group, the same steps were applied, but the gauze was soaked in PVP-I instead of Shellac. The procedure was to be repeated once daily in the conventional treatment group and when needed, such as after showering or removal of dressing in the Shellac group. All patients were asked to visit the clinic every month or when signs of inflammation or fever were observed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient death
2. Rates of surgical amputation and /or debridement of gangrenous tissues
3. Rates of auto-amputation of gangrenous tissues
4. Performance of vascular revascularization procedure

Secondary outcome measures
1. Rates of local and/or systemic infection
2. Extension of gangrene to adjacent healthy tissues
3. Progression of dry to wet gangrene

Overall study start date
01/01/2010

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Patients with diabetes
2. Patients who presented with peripheral dry well-demarcated gangrene in their feet who were offered the option to wait for non-surgical autoamputation
3. Geriatric, bed-ridden patients with diabetes who refused amputation and/or were contra-

indicated for re-vascularization or surgery
4. Any patient above 40 years of any gender

Patients were allowed to withdraw at any time.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15 in each arm of the study. total 30

Key exclusion criteria
1. Patients with evidence of wet/infected gangrene that was confirmed by microbiological culture
2. Patients currently on antibiotics. These patients could enter the study 1 week after complete cessation of initial antibiotic therapy.
3. Patients with uncontrollable local and/or systemic infection requiring antibiotics, surgical amputation and/or local debridement
4. Patients in whom infection showed signs of spreading

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Abdulaziz University KAU
Jeddah
Saudi Arabia
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Sponsor information

Organisation
The Scientific Chair of Sheikh Mohammad Hussein Al-Alamoudi for Diabetic Foot Research (Saudi Arabia)

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Sponsor type
University/education

ROR
https://ror.org/01vv03303

Funder(s)

Funder type
University/education

Funder Name
The Scientific Chair of Sheikh Mohammad Hussein Al-Alamoudi for Diabetic Foot Research (Saudi Arabia)

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	01/06/2013		Yes	No