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Treatment of Diabetic Foot Wounds by Vacuum-Assisted Closure (VAC®)

Submission date	Recruitment status	[X] Prospectively registered
13/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/07/2010	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DRKS00000059

Study information

Scientific Title
Treatment of Diabetic Foot Wounds by Vacuum-Assisted Closure (VAC®): A multicentre, randomised controlled trial

Acronym
DiaFoVAC

Study objectives
This randomised controlled trial (RCT) comparing vacuum-assisted closure and conventional moist wound therapy (CMWT) for diabetic foot wounds was designed in order to:
1. Prove that VAC® therapy leads to complete healing of diabetic foot wounds more of-ten and earlier as compared to conventional moist wound therapy
2. Show that VAC® therapy is safe and effective also when provided in an ambulatory care setting
3. Generate more data on optimal patient selection and optimal combination of VAC® therapy with surgical closure

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local ethics committee (Ethik-Kommission der Universität Witten/Herdecke) approved on the 8th of May 2009 (ref: 12/2009)

Study design
Multicentre randomised controlled clinical superiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetic foot syndrome / chronic or amputational diabetic foot wound / wound treatment

Interventions
Participants will be randomised to receive either:
1. Intervention: Vacuum-assisted-closure® based on negative pressure wound therapy (V.A.C® NPWT)
2. Control / Comparator: Conventional Moist Wound Therapy (CMWT) according to current available evidence based guidelines

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Time until complete (100%) wound closure, defined by the following criteria:
1. Full (100%) re-tepithelialization of the wound (i.e. no granulation tissue visible)
2. No drainage
3. No need for wound dressing

Key secondary outcome(s))
1. Clinical endpoints
1.1. Wound size (area of wound opening, maximal length and width)
1.2. Composition of wound tissue (percentage of epithelia layer, granulation tissue and fibrin)
1.3. Pain in wound surrounding (until wound closure and at 12 months)
1.4. Incidence and time of wound bed preparation
1.5. Secondary resections and amputations
1.6. Recurrence of wound or ulcer at same site
1.7. Complication rates (local and systemic)
1.8. Total complication rate
1.9. Mortality of any cause (within 12 month)
2. Health economic endpoints
2.1. Number of dressing changes
2.2. Length of treatment
2.3. Length of hospital stay
2.4. Time until orthopedic footwear supply possible
2.5. Time until return to work
2.6. Quality-of-life during treatment
2.7. Quality of life after Healing (at 6 and 12 months)
2.8. Patient satisfaction
2.9. Costs (in and out hospital)

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Evidence of diabetes mellitus type I, II or III as defined by the necessity for antidiabetic drugs for ≥ 12 months
2. All wounds corresponded to University of Texas grade 2 or 3 in depth
2.1. either a chronic wound which is planned to receive radical surgical debridement
2.2. or an amputational wound which results from a planned below-ankle amputation
3. Participant has given written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnancy
2. Age <18 years

3. Missing Compliance
4. Untreated or refractory phlegmona or untreated osteomyelitis of the wound
5. Exposed blood vessels in or around the wound that can't be protected or have a heightened risk for a bleeding with relevant circulation effects
6. Any revascularization procedure or amputation of the same extremity within the last 5 days
7. Indication for above-ankle amputation of the same extremity
8. Any extreme defective position of toes, foot or the whole extremity which could lead to ischemia of the wound area and impair wound healing
9. Evidence of inadequate perfusion
9.1. via MR angiography within the last 3 month or
9.2. sonographic confirmation of absence of peripheral pulse at A. tibialis posterior or A. dorsalis pedis) or
9.3. transcutaneous oxygen measurements of the dorsum of the foot ≤30 mmHg or
9.4. ankle brachial indices ≥0,7 and ≤1.2 and toe pressure at ≤30 mmHg
10. Renal insufficiency with need for dialysis
11. Anemia which is not caused infection
12. Long term use of oral (p.o.) steroids (> 30days)
13. Chronic anticoagulation except acetylsalicylate, clopidogrel (e.g. by vitamin K an-tagonists) at screening that can't be bridged to heparins during participation in the trial
14. Nerve lesions or active Charcot disease (Diabetic neuro-osteoarthropathy) of either lower extremity that will interfere with wound treatment
15. Malignancy in the wound or the periwound area or any other malignancy requiring immunosuppressant therapy or chemotherapy
16. Wounds resulting from burns, untreated cellulitis or collagen vascular disease
17. Presence of necrotic tissue that cannot be debrided
18. Concomitant severe skin disease that may impair wound healing
19. Connective tissue disease that might impair wound healing
20. Hematological disorders or condition that might impair wound healing
21. History of significant chronic anemia as evidenced by hemoglobin concentration of < 10 g/dl within 30 days of screening
22. Any kind of chronic venous insufficiency (CVI) or CVI that leads to varicose eczema, lo-cal inflammation and an increased risk of ulcers
23. Use of VAC® negative pressure wound therapy (NPWT) or any other suction device system on the study wound ≤ 8 days prior to screening
24. Previous treatment with hyperbaric oxygen therapy (HBO) or normothermic therapy in the past 8 days
25. Application of recombinant or autologous growth factors on the study wound ≤ 8 days prior to screening
26. Application of skin or dermal substitutes and dressings with living cells capable of producing growth factors (e.g. Oasis®, Apligraf®, Dermagraft™, or Integra®) on the study extremity < 15 days prior to screening
27. Allergy to any disposal component of the VAC® or MWT used materials
28. Simultaneous participation in other interventional trials interfering with one of the approaches in this trial
29. Previous participation in this trial

Date of first enrolment
01/06/2011

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Germany

Study participating centre
Institut für Forschung in der Operativen Medizin
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Sponsor information

Organisation
Private University of Witten/Herdecke gGmbH (Germany)

ROR
https://ror.org/00yq55g44

Funder(s)

Funder type
Industry

Funder Name
Kinetic Concepts, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration