ISRCTN42122226 https://doi.org/10.1186/ISRCTN42122226

Enhancing self-care in leg ulcer patients: tandem practices as a model for interdisciplinary care

Submission date	Recruitment status	[_] Prospectively registered
03/07/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2010	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Monika A. Rieger

Contact details
University of Witten / Herdecke, Alfred-Herrhausen-Str. 50
Witten
Germany
58448
+49 (0)2302 926712
monika.rieger@uni-wh.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01GL0507

Study information

Scientific Title

Acronym
TANDEM study

Study objectives
Does an additional nurse-led education programme improve wound healing, Health Related Quality of Life (HRQoL), and recurrence rates in patients suffering from venous leg ulcers treated by general practioners?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University of Witten/Herdecke (reference number: 21/2005), date of approval: 17/05/2005 (first amendment: 28/10/2005, second amendment: 22/06/2006).

Study design
Open, multicentre randomised controlled trial (randomisation on the level of general practioners' practices)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Venous leg ulcers

Interventions
Nurses offer an education programme to patients receiving usual care by their general practitioner (GP). In addition, the nurse specialist offers support to the medical doctor himself. The content of the nurse-led education programme was based on an evidence-based self-care activity catalogue which was derived from national and international clinical guidelines. The teaching of the nurse specialists was based on the theory of self-care competence. The control group received usual care from their GP, but not the nurse led education programme.

Both groups, the medical doctors in the intervention and in the control group, received written information on the "state-of-the- art"-therapy of patients with venous leg ulcers (short and comprehensive version of the actual official guideline).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
At 12 weeks (+/- two weeks)(t2):
1. Wound healing (proportion of healed leg ulcers)
2. Reduction of wound area (measured by digital planimetry)
3. Health-related quality of life (Freiburg Life Quality Assessment (FLQA), scale 1: physical complaints)

Secondary outcome measures
At six weeks (+/- one week)(t1), 12 weeks (+/- two weeks)(t2), 24 weeks (+/- four weeks)(t3) and 52 weeks (+/- four weeks)(t4) secondary outcomes:
1. Characteristics of healing (using the Leg Ulcer Measurement Tool [LUMT])
2. Health-related quality of life using the FLQA
3. Self-care competence
4. Health economic evaluation (use of resources
5. Costs of the intervention
6. Satisfaction and personal opinion of all concerned subjects (patients, medical doctors and their teams, relatives, nurses)

Overall study start date
01/12/2005

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Patients suffering from venous leg ulcers (stadium C6 according to CEAP classification)
2. Patients receiving treatment in a study practice
3. Patients have an ability of self-care (or the control of dependent care e.g. by relatives)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
Exclusion criteria (before the study i.e.: no inclusion):
1. Other stadium of chronic venous insufficiency
2. Other etiology of the leg ulcer (e.g. arterial insufficiency, ulcus mixtum, diabetic foot)
3. Cognitive impairment (hindering self-care)
4. Insuffient competence of the German language
5. Inability to read
6. Parallel participation in another clinical trial

Exclusion criteria (during the study):
1. Change of the general practitioner during the first six months after inclusion in the study
2. Ending of the study participation of the general practitioner
3. In-patient treatment (at least for 14 days)
4. Newly developed severe illness (hindering self-care)

Date of first enrolment
01/12/2005

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Germany

Study participating centre
University of Witten / Herdecke, Alfred-Herrhausen-Str. 50
Witten
Germany
58448

Sponsor information

Organisation
Federal Ministry of Education and Research (Bundesministerium fuer Bildung und Forschung) (BMBF) / German Aerospace Center (DLR)

Sponsor details
BMBF
Projektträger im DLR Gesundheitsforschung,
Heinrich-Konen-Str. 1

Bonn
Germany
53227

Sponsor type
Not defined

Website
www.pt-dlr.de

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Main Sponsor:

Funder Name
Federal Ministry of Education and Research (BMBF)/German Aerospace Center (DLR) (ref. number: 01GL0507)

Funder Name
Additional funding:

Funder Name
B. Braun foundation (Melsungen, Germany)

Funder Name
Bauerfeind AG (Zeulenroda, Germany)

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	14/08/2009		Yes	No