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Physical suffering in patients with venous disease

Submission date	Recruitment status	[_] Prospectively registered
16/07/2019	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
23/07/2019	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
28/05/2021	Circulatory System	

Plain English summary of protocol

Background and study aims
Superficial venous disease (SVD) is a very common disease and much research has been done towards finding the ideal treatment and discovering the pathophysiology of SVD. Not much is known about the psychological burden of SVD. Current guidelines and scientific publications tend to focus on clinical and physiological aspects of SVD. The aim of this study was to relate the changes in Quality-of-Life(QoL) after SVD treatment to possible changes in psychic distress (PD).

Who can participate?
Patients aged 18 years and older with SVD.

What does the study involve?
Patients with SVD are divided into two groups. One group is treated by sclerocompression therapy (SCT), the other using laser ablation (LA), radiofrequency ablation (RFA), or phlebectomy (PHL). Patients complete questionnaires to assess quality of life and mental health at baseline, 6- and 12-months.

What are the possible benefits and risks of participating?
Benefits: No direct benefits, but this research will improve future treatment of the condition.
Risks: None

Where is the study run from?
1. Zuyderland Medical Center
2. Maastricht University Medical Center
3. Centrum Oosterwal
4. Westfriesgasthuis
5. Braam Kliniek
All in the Netherlands

When is the study starting and how long is it expected to run for?
January 2012 to December 2013

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Tim Sigterman
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
11-4-110

Study information

Scientific Title
The relationship between psychic distress and impairment of disease-specific quality-of-life compared between sclerocompression therapy and invasive treatments in patients with superficial venous disease during a one-year follow-up

Study objectives
We hypothesize that an increased clinical severity and impaired quality of life (QoL) in superficial venous disease (SVD) will also increase psychic distress (PD) and that an invasive intervention (group 2) will improve outcome compared to sclerocompression therapy (SCT) (group 1).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/11/2011, Medical Ethical Committee of the Maastricht Univerisity Medical Center (P Debyelann 25, Maastricht, 6229 HX, The Netherlands; +31(0)43-387 65 43; secretariaat.mec@mumc.nl), ref: WMO/METC 11-4-110

Study design
Prospective cohort

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Varicose veins

Interventions
A prospective cohort was set up with the assistance of five specialized vein clinics in the Netherlands.

Patients were divided into two groups:
1. C1-C3 patients treated by SCT
2. C1-C6 patients treated invasively laser ablation (LA), radiofrequency ablation (RFA), phlebectomy(PHL)

Patients completed a disease-specific QoL questionnaire (CIVIQ-20) and a questionnaire to assess PD (HADS) at baseline, 6- and 12-months.

C1-C6 refer to the visual classification of the severity of the SVD:
C0 – the lowest degree in severity, means that there is no sign of venous disease when looking at the leg
C1 – means that the person has spider or reticular veins when looking at the leg
C2 – means that varicose veins are present when looking at the leg
C3 – denotes the presence of edema (swelling) of the ankle. Best visualized from the back rather than the front.
C4a,b – includes pigmentation (darkening) of the skin, eczema (redness, itching), lipodermatosclerosis (hardening of the soft tissues), and atrophie blanche (a whitish skin area)
C5 – means that a healed venous ulcer is present when looking at the leg
C6 – is the most severe category, means that an active open venous ulcer is seen on the skin

Intervention Type
Procedure/Surgery

Primary outcome(s)
Quality of life measured using the CIVIQ-20 questionnaire at baseline, 6- and 12-months

Key secondary outcome(s))
Depression and anxiety measured using the HADS at baseline, 6- and 12-months

Completion date

31/12/2013

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Fluent in Dutch language
3. C1 to C6 (CEAP) class intended to be treated with either laser(LA), radiofrequency ablation (RFA), phlebectomy(PHL) or sclerocompression therapy (SCT)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
442

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Zuyderland Medical Center
Henri Dunantstraat 5
Heerlen
Netherlands
6459

Study participating centre
Maastricht University Medical Center
Prof Debeyeplein 30
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Study participating centre
Centrum Oosterwal
Comeniusstraat 3
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Study participating centre
Westfriesgasthuis
Maelsonstraat 3
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1624 NP

Study participating centre
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Assen
Netherlands
9405 PS

Sponsor information

Organisation
Zuyderland Medical Center

ROR
https://ror.org/03bfc4534

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the general investigator, A. Krasznai akrasznai@zuyderland.nl on reasonable request

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/05/2021	28/05/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes