

Physical suffering in patients with venous disease

Submission date 16/07/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/05/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 University 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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

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 measure

Quality of life measured using the CIVIQ-20 questionnaire at baseline, 6- and 12-months

Secondary outcome measures

Depression and anxiety measured using the HADS at baseline, 6- and 12-months

Overall study start date

01/06/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

442

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

Maastricht

Netherlands

6229

Study participating centre

Centrum Oosterwal

Comeniusstraat 3

Alkmaar

Netherlands

1817 MS

Study participating centre

Westfriesgasthuis

Maelsonstraat 3

Hoorn

Netherlands

1624 NP

Study participating centre

Braam Kliniek

Zoom 10

Assen

Netherlands

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Sponsor information

Organisation

Zuyderland Medical Center

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

www.zuyderland.nl

ROR

<https://ror.org/03bfc4534>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Submitted to Journal of Vascular Surgery: venous and lymphatic disorders

Intention to publish date

01/10/2019

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