Electrosclerotherapy for capillary malformations

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25691

Source
Nationaal Trial Register

Health condition

vascular malformations
capillary malformations
port-wine stains
wijnvlekken
capillaire malformaties

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

- (Change in) global assessment of color, thickness, nodularity, pliability, surface area and overall improvement by both the patient and a blinded observer using a global assessment score and the POSAS instrument.

- In terms of safety, we will investigate the number and type(s) of adverse events.

Secondary outcome

- (Change in) color measured using colorimetry

- (Change in) perfusion of the capillary malformations, measured using optical imaging techniques.

Study description

Background summary

In this pilot RCT, we will determine the feasibility and explore the efficacy and safety of electrosclerotherapy as a novel treatment option for capillary malformations. This is a method in which we combine intralesional injections with bleomycin with electroporation (= generating an electric field over the tissue). This is a double-blind (patient and outcome assessor) randomized within-patient controlled trial. All participants undergo one intervention session in which 3 homogeneous 1.5x1.5 cm parts of the capillary malformation are randomly allocated to [1] electrosclerotherapy, [2] bleomycin injection without electroporation or [3] no treatment. Outcome will be measured using patient- and outcome assessor-reported global changes in appearance using the validated POSAS score. Furthermore, adverse events will be reported. Changes in color and perfusion of the capillary malformation will be measured using colorimetry and optical imaging, respectively.

Study objective

Capillary malformations (¡®port-wine stains¡¯) are congenital abnormalities of the capillary vessels of the skin, causing a red or purple color. Laser therapy is currently the only widely accepted treatment option, but treatment response is suboptimal in approximately half of patients. In capillary malformations with hypertrophy, increased thickness of the (sub)cutaneous tissue, treatment response is even poorer. Hence, there is a need for an alternative treatment option for capillary malformations.
Intralesional bleomycin injections (sclerotherapy) are commonly used to treat vascular malformations of larger sized vessels, but cannot be used in capillary malformations because the vessel diameter is too small for accurate intravascular injections.
Therefore, bleomycin cannot reach the endothelial cells where it has its therapeutic sclerosing effect.

¡®Electroporation' is a physical phenomenon that increases the permeability of cell membranes through the exposure of cells to an electric field, which allows molecules and drugs to easily cross cell membranes. The combination of electroporation and the regular intralesional bleomycin injections (¡®electrosclerotherapy¡¯) could facilitate localized bleomycin delivery to endothelial cells and subsequent vascular depletion, ultimately leading

to regression of the capillary malformation. Electrosclerotherapy has been safely used in many skin lesions with high effectiveness rates, especially in vascular tumors. We hypothesize that electrosclerotherapy can also be a feasible and safe alternative treatment option for capillary malformations.

Study design

The patient visits the hospital 3 times: [1] treatment visit (t=0), [2] wound check visit (t=1 week) and [3] outcome measurement visit (t=7 weeks).

Intervention

All participants undergo one intervention session in which 3 homogeneous 1.5x1.5 cm parts of the capillary malformation are randomly allocated to [1] electrosclerotherapy, [2] bleomycin injection without electroporation or [3] no treatment.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with ¡Ý1 completely or partially hypertrophic capillary malformation not exclusively located in the skin of the face, the skin overlying joints or in mucosal tissue

- Age ¡Ý 18 years

- Fitzpatrick skin type 1-3 without evident sun tan

Exclusion criteria

- Patients with capillary malformations exclusively located in the face, in the skin overlying joints or in mucosa

- Pregnant or breastfeeding women

- Women with childbearing potential not using contraception

- Patients with chronic renal dysfunction of GFR <50 ml/minute

- Patients with chronic pulmonary dysfuction, active pulmonary infections or previous bleomycin lung toxicity

- Patients with ataxia teleangiectasia

- Patients with previous allergic reactions to bleomycin

- Patients who already received the maximum dose of bleomycin (400 units mg or 400000 IU/m2)

- Patients with implanted electrical devices such as pacemakers or ICD's

- Patients with clinically manifested arrhythmia

- Patients with epilepsy

- Patients who are not able to return to the hospital for follow-up visits

- Patients who are likely not able to understand the terms and risks of the study (e.g. cognitive impairment)

- Legally incompetent adults

- Patients of which informed consent was not obtained

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-12-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6038
NTR-old	NTR6169
Other	NL58824.018.16 : 2016_239

Study results

Summary results

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