Electrosclerotherapy as a novel treatment option for capillary malformations: a pilot study

Published: 09-11-2016
Last updated: 15-04-2024

Determine the feasibility and explore the efficacy and safety of electrosclerotherapy as a novel treatment option for capillary malformations.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Blood and lymphatic system disorders congenital
Study type	Interventional

Summary

ID

NL-OMON45598

Source
ToetsingOnline

Brief title
Electrosclerotherapy for capillary malformations

Condition

- Blood and lymphatic system disorders congenital

Synonym
Capillary malformations, port-wine stains

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,IGEA medical

Intervention

Keyword: bleomycin, capillary malformations, port-wine stains, vascular malformations

Outcome measures

Primary outcome

The study parameters are (change in) global assessment of color, thickness,

nodularity, pliability, surface area and overall improvement by both the

blinded patient and a blinded observer using a global assessment score and the

POSAS instrument.

Secondary outcome

Number and type(s) of adverse events.

(Change in) objective color measurement using colorimetry.

(Change in) perfusion measured using optical imaging.

Study description

Background summary

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 objective

Determine the feasibility and explore the efficacy and safety of electrosclerotherapy as a novel treatment option for capillary malformations.

Study design

Prospective, randomized, within-patient controlled pilot study.

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.

Study burden and risks

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). The treatment procedure consists of local anesthesia, injections with bleomycin and/or non-invasive electroporation. Potential risks of treatment are local bleeding, wound healing disorders and allergic reactions to bleomycin. Potential benefits are reduction of red color, hypertrophy/nodularity and bleeding symptoms. Outcome measurement procedures are non-invasive, using patient and observer scores, colorimetry and optical imaging.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with *1 completely or partially hypertrophic capillary malformation not exclusively located in the skin of the face, the skin overlying joints or in mucosal tissue
- Age * 18 years
- Fitzpatrick skin type 1-3 without evident sun tan

Exclusion criteria

- 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 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)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Cliniporator
Registration:	Yes - CE outside intended use
Product type:	Medicine
Brand name:	Bleomedac
Generic name:	Bleomycin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	09-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2016-003238-26-NL
CCMO	NL58824.018.16