prospective randomised controlled study for superficial hemangioma: pulsed dye laser treatment versus wait-and-see-policy

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Our aim is to do a prospective, randomised controlled study to ascertain whether PDL treatment for superficial hemangioma influences- complete remission rate- growth (involution/ groth stop, proliferation)- cosmetic outcome- complications/ adverse...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33619

Source
ToetsingOnline

Brief title
pulsed dye laser vs wait-and-see-policy for superficial hemangioma

Condition

- Other condition

Synonym
hemangioma, strawberry mark

Health condition

hemangiomen

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: haemangioma, hemangioma, laser

Outcome measures

Primary outcome

Clearance : Complete remission or minimal residual signs (teleangiectasia,

faint redness, minimal atrophic scarring, minimal pigment changes)

Secondary outcome

- redness

- Stop growth

- Tumor involution/ regression

- Proliferation

- Adverse outcome/ complication (required other treatment, ulceration,

bleeding, infection, dyspigmentation, scars)

- Residual signs

- Parents quality of life

- Cosmetic outcome

- Cost benefit

Study description

Background summary

Childhood haemangioma is the most common soft tissue tumour of infancy, occurring in
10 % of children under the age of one year. Less than 10% is present at birth, while 90% appear within the first 4 weeks of life. The hallmark of haemangiomas is a rapid proliferative phase, and a slower involutional phase. There are three kinds of hemangioma: superficial, compound and subcutaneous. They all start out as a superficial hemangioma.

During the proliferative phase complications can arise, such as bleeding, infection, functional impairment due to obstruction of vital structures and disfigurement. Most hemangioma are located on the face. Haemangioma with complications that need treatment are more likely to be located on the face. The anual resulution rate of hemangioma is 10% per year. In the first year, around 5% will undergo complete remission. Therefore, the standard policy in the Netherlands is a wait-and-see-policy.

Regression results in a normal skin texture in most patients, but residual skin changes like teleangiectasia, atrophy, sagging, fibro fatty tissue residuum and scarring, will remain in up to 50% of the patients. The most important prognostic factors for the permanent damage left by involutive haemangiomas are size, involvement of subcutaneous structures, and associated complications. Haemangioma, especially located in the face, often cause great psychosocial morbidity, affecting both parent and child. Therefore, it is desirable to have the haemagioma removed before the child enters school.

The quest for a therapy that eliminates haemangiomas before development of complications and without systemic or cutaneous adverse effects, has been difficult. Treatment with the Pulsed Dye laser (PDL) is the gold standard for treating vascular lesions. It is well established as the most effective, safe treatment for port-wine-stains in children. A PDL treatment is easy feasible in children under the age of 1 year and has little side effects.

Study objective

Our aim is to do a prospective, randomised controlled study to ascertain whether PDL treatment for superficial hemangioma influences

- complete remission rate
- growth (involution/ groth stop, proliferation)
- cosmetic outcome
- complications/ adverse events

Furthermore we will look at parent quality of live and cost -benefit

Main objective:
Clearance: Complete remission/ minimal residual signs

Secondary objective:
1. Stop growth
2. Regression
3. Proliferation
4. Reduction of redness
5. Residual signs
6. Adverse outcome/ complication (required other treatment, ulceration, bleeding,
infection, dyspigmentation, scars)
7. Parents quality of life
8. Cost of treatment

Study design

prospective randomised controlled intervention study

Standardised Photographs: each visit
Color measurement: begin and
endpoint
length + width + volume measurement each visit
Color duplex sonography: begin age
3months, 6 months, 9 months and endpoint

Questionnaire parents quality of life: before and
after last treatment
Cost of treatment: last
visit

Treatment frequency: 2-6 weeks interval
Treatment will be continued until complete remission; stop proliferation; if further treatment does not give improvement of the hemangioma; when there are complications requiering other treatments; when the result is optimal and further treatment will increase the chance of side effects; when the child gives a lot of resistence to the treatment (usually after the age of 1 year)

Intervention

Pulsed dye laser 595nm; spot diameter 7mm; 30/10 epidermal cooling; fluence 7-15J/cm^2; pulse duration 0,45-40ms

Study burden and risks

Treatment frequency: 2-6 weeks interval
Follow up: every 2-6 weeks, up to 1 year. If complete remission is acomplished before one year of age of the patient, follow up is the same as in the control

group.
Treatment duration: seconds - 1 min.
Physical discomfort: children will be treated while they are being fed by their care takers.
Discomfort (painful shocks and epidermal cooling) will only take a few seconds.
General/ local anaesthesia: no
Standardised Photographs: every visit
Color measurement: begin and endpoint
Color duplex sonography: begin, age 3 months, 6 months, 9 months, endpoint

complication/ adverse outcome (0-4%): atrophic scarring, dyspigmentation, ulceration, infection

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

patients< 6 months
untreated superficial hemangioma
maximum diameter < 5 cm
dept up to the papillairy dermis

Exclusion criteria

subcutaneous/ compound hemangioma
ulcerating hemangioma
hemangioma associated with neurocutaneous syndromes
hemangioma with very high risk of visual/ heardamage/ airway obstruction

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-02-2009

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL23087.060.08