Prospective study in congenital giant melanocytic naevi after curettage and laser ablation with the Erbium YAG laser (left-right comparison)

Published: 15-10-2008
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Proof that laser treatment will be better than the routine method using curettage. Besides it is claimed that laser treatment is less painfull.This will be assessed by photography, in which only black white (grey) evaluations are made. Colours are...

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital and hereditary disorders NEC
Study type	Interventional

Summary

ID

NL-OMON31799

Source
ToetsingOnline

Brief title
Treatment of congenital giant melanocytic naevi: curettage vs laserablation

Condition

- Congenital and hereditary disorders NEC
- Pigmentation disorders
- Skin and subcutaneous tissue therapeutic procedures

Synonym
birthmarks, congenital moles

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: congenital giant melanocytaire naevi, curettage, Erbium YAG laser, laserablation

Outcome measures

Primary outcome

Clinical and photographically observation.

Secondary outcome

Pain adjustment

Study description

Background summary

The current treatment, with curettage leads to not-completely satisfied results. It is claimed that laser ablation leads to better results and besides it would be less painful.

Study objective

Proof that laser treatment will be better than the routine method using curettage. Besides it is claimed that laser treatment is less painfull.
This will be assessed by photography, in which only black white (grey) evaluations are made. Colours are influenced by environmental factors.
Besides we will proof that laser treatment will have a less negative effect on painscores and quality of life.
The design of the study (left - right) makes it difficult to evaluate, but we think that it is possible to indicate a difference between left and right (especially with respect to the painscore).

Study design

Left, right randomised.

Intervention

surgical treatment

Study burden and risks

Not more than routinely happens.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patients with congenital giant melanocytic naevus

Exclusion criteria

Nevi smaller than 20 cm,
Another systemic disease.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-10-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL16729.078.07