

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of efficacy of combination PDL laser with topical propranolol and PDL laser alone in treatment of infantile hemangioma.

Protocol summary

Summary

A randomized single blinded without placebo control uni-central study. Patients involved with infantile hemangioma who are visited in dermatology clinic of Razi Hospital who are meeting Inclusion and Exclusion criteria are involved in this study. Inclusion criteria : 1- Hemangioma located in non-sensitive area (include nose-ear-eyelid-lips) 2-Patient compliance with study 3-No previous treatment (with systemic corticosteroids or other drugs) received in the last 3 months. 4-Patients should not have any systemic involvement (congenital heart disease-renal disease) 5-Hemangioma in the proliferative phase of evolution (age < 2 years). Exclusion criteria: 1-no response after 4 weeks of treatment 2-Allergic reaction to anyone of topical drugs. 3-Side effects of topical propranolol (e.g erythema, pruritus, inflammation.....) Patient who meet inclusion criteria are randomized to two groups A, B. Table of random numbers will be helpful to divide patients. Group A of patients treated with PDL every 4 weeks while patients in group B in addition to the PDL laser every 4 weeks will receive topical ointment propranolol daily as a thin layer to cover the entire lesion up to 3 months. PDL with the following laser parameters will be done for all patients: Spot Size: 7mm, Fluence: 12J/Cm², Duration 1.5ms, DCD = 40/40. Before treatment of all lesions will be taken a photograph with a view Close-up digital photo camera. After 4, 8, 12 and 16 weeks of treatment patients are followed. Reduction in lesion size by comparing images taken before and after treatment of lesions based on the VAS (Visual Analogue Scale) will be performed. Accordingly, less than 25% reduction in lesion size is equivalent to 1 score- between 25% to 50% reduction in size is equivalent to 2 scores, reduction between 50% to 75% of size is equivalent to 3 and finally more than 75% reduction in size is equivalent 4 score. Comparison of images before and after treatment by two dermatologists who have not participated in the study will be performed and an estimation of average of both scores will be the

final result of size reduction. The T-test will be used to compare results and to determine significant differences

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110137787N1**

Registration date: **2012-01-08, 1390/10/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-08, 1390/10/18

Registrant information

Name

Mona Abdolreza

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of efficacy of combination PDL laser with topical propranolol and PDL laser alone in treatment of infantile hemangioma.

Public title

Efficacy of PDL laser and topical propranolol in treatment of infantile hemangioma.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion crateria : 1-Hemangioma located in non-sensitive area(include nose-ear-eyelid-lips) 2-Patient compliance with study 3-No previous treatment(with systemic corticosteroids or other drugs) received in the last 3 months. 4-Patients shold not have any systemic involvement(congenital heart disease-renal disease) 5- Hemangioma in the proliferative phase of evolution(age<2 years). Exclusion crateria: 1-no response after 4 weeks of treatment 2-Allergic reaction to anyone of topical drugs. 3-Side effects of topical propranolol (e.g erythema,pruritus,inflamation.....)

Age

To 2 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 28

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University Of Medical Sciences

Street address

Tehran-Enghelab Eslami Square

City

Tehran

Postal code**Approval date**

2011-11-05, 1390/08/14

Ethics committee reference number

1661, 130, 90 ,ص

Health conditions studied**1****Description of health condition studied**

Infantile Hemangioma

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Efficacy of topical propranolol with PDL laser and PDL laser alone in treatment of infantile hemangioma

Timepoint

0-4-8-12-16 weeks

Method of measurement

Evaluation and comparision of lesion photographs according to VAS(Visual Analogue Scale)

Secondary outcomes**1****Description**

improvement of overall health of patient

Timepoint

4-8-12-16 weeks after initial treatment

Method of measurement

Patients parents

Intervention groups**1****Description**

Perform PDL laser(3 sessinns)with 4 weeks interval +daily application of topical propranolol by the patient up to 3 months.

Category

Treatment - Drugs

2**Description**

PDL laser alone is performed (3 sessions with 4 weeks interval)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital of Dermatology

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotouhi

Street address

Tehran-Enghelab Eslami Square

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Razi Hospital

Full name of responsible person

Dr. Mona Abdolreza

Position

Resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty