Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Summary

A ranomised 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 crateria are involved in this study. 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.....) 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 phtograph 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
Iran (Islamic Republic of)
Phone
+98 21 5561 8989
Email address
abdolreza@razi.tums.ac.ir

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
Street address
Razi hospital-Vahdate Islami Street-Tehran
City
Tehran
Postal code
Phone
+98 21556099513
Fax
Email
abdolreza@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mona Abdolreza
Position
Resident
Other areas of specialty/work
Street address
Razi hospital-Vahdate Islami Street-Tehran
City
Tehran
Postal code
Phone
+98 21556099513
Fax
Email
abdolreza@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Razi hospital
Full name of responsible person
Dr.Mona Abdolreza
Position
Resident
Other areas of specialty/work
Street address
Razi hospital-Vahdate Islami Street-Tehran
City
Tehran
Postal code
Phone
+98 21556099513
Fax
Email
abdolreza@razi.tums.ac.ir
Web page address
www.tums.ac.ir

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