Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of effectiveness of radiofrequency ablation in beta thalassemia patients, considering hematologic parameters

Protocol summary

Summary

In this study, we investigated the efficacy and safety of RF ablation in hematological parameters (rise of Platelet and hemoglobin, need of blood transfusion) in patients with Thalassemia Intermedia (TI). Inclusion criteria was presence of Cooley’s anemia in patients and exclusion criteria was positive Coomb's test. RF ablation of spleen had been performed in 15 TI children under general anesthesia using a Cooltip Radionics RF probe. These patients have been regarded as RFA group. Nine patients with TI who underwent partial splenectomy during the last 3 years and another 14 patient group with TI who underwent total spelenectomy during 3 years prior to study, were also enrolled as the first and second control groups (CG1 and CG2).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712141738N1**
Registration date: **2009-05-29, 1388/03/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-05-29, 1388/03/08

Registrant information

Name

Mehdi Naderifar

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 3233

Email address

nabavia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2008-07-20, 1387/04/30

Expected recruitment end date

2009-01-20, 1387/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of effectiveness of radiofrequency ablation in beta thalassemia patients, considering hematologic parameters

Public title

Investigation of effectiveness of radiofrequency ablation in beta thalassemia patients, considering hematologic parameters

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:beta thalassemia Exclusion criteria: positive direct or indirect coombs

Age

From **5 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences Ethics commitee
Street address
Shiraz University of Medical Scieces
City
Shiraz
Postal code
Approval date
2008-07-20, 1387/04/30
Ethics committee reference number
CT-87-4150

Health conditions studied

1

Description of health condition studied
Beta thalassemia
ICD-10 code
D56.1
ICD-10 code description
Cooley's anaemia

Primary outcomes

1

Description
Level of Hb
Timepoint
3 month follow-up period
Method of measurement
CBC

2

Description
Platelet count
Timepoint
3 month follow-up period
Method of measurement
CBC

Secondary outcomes

1

Description
Need to transfusion
Timepoint
3 months follow-up period
Method of measurement
transfusion volume and intervals

Intervention groups

1

Description
Radiofrequency ablation of spleen in beta thalassemia using Cooltip Radionics RF Probe.
Category
Other

2

Description
Partial splenectomy
Category
Treatment - Surgery

3

Description
Total splenectomy
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazee Hospital
Full name of responsible person
Mehdi Naderifar
Street address
Radiology Ward, Namazee Hospital
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Street address
Shiraz University of Medical Sciences, Zand Ave.
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Naderifar
Position
Radiology resident
Other areas of specialty/work
Street address
Radiology Ward, Namazee Hospital
City
Shiraz
Postal code
Phone
+98 71 1647 3233
Fax
+98 71 1647 3233
Email
mehdinaderifar2000@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
SUMS
Full name of responsible person
Ali Reza Rasekhi
Position
Associate Professor
Other areas of specialty/work
Street address
Radiology Ward, Namazee Hospital
City
Shiraz
Postal code
Phone
+98 71 1647 3233
Fax
+98 71 1647 3233
Email
mehdinaderifar2000@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Naderifar
Position
Resident
Other areas of specialty/work
Street address
Radiology Ward, Namazee Hospital
City
Shiraz
Postal code
Phone
+98 71 1647 3233
Fax
+98 71 1647 3233
Email
mehdinaderifar2000@yahoo.com
Web page address

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