Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Intravascular Laser Therapy on improvement of Acute Kidney Injury(AKI) with Urinary NGAL and Serum Cr

Protocol summary

Study aim

The purpose of this study was to investigate the effects of intravenous laser on the improvement of patients with acute renal injury using urinary NGAL and serum creatinine.

Design

In this randomized clinical trial, 40 patients with intra renal acute renal injury in all three groups of RIFLE were divided into control and treatment groups.

Settings and conduct

Patients with acute renal injury in all three groups of RIFLE who are referred to the Shahdai Tajrish hospital for treatment are included in the criteria for inclusion in the study. All patients are randomly assigned 1: 1 randomly divided into two groups .The group assigned to the subject is buried in dark envelopes. The envelope will be opened by a doctor only after initial evaluations in each person, and neither patients nor clinical evaluators will know their treatment group. Etiology factors include sepsis, rhabdomyolysis, age, diabetes, hypertension, AKI severity and drugs are matched in both groups. Patients undergoing intravenous laser therapy are using infrared radiation. This method is non-thermal and non-toxic, using a continuous infrared beam or near infrared 600 nm with a power output of 5 mW. In this method, the laser light directly irradiates through a sterile disposable catheter. Two millimeters of optical fiber (200 nm in diameter and silicon dioxide) enter the vein and circulate in the circulation. This procedure is just like the injection of serum. Intravenous light red light, in this study with a power of 5 mW for 30 minutes. The intravenous laser is performed for 7 sessions per day. The NGAL level of urine and serum creatinine is measured and recorded before and after treatment. The control group is under the control of Sham Laser.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with acute renal injury with intra renal causes in all RIFLE classes; Full satisfaction for participation in the study and completion of treatment and follow up; Exclusion criteria: Patients with pre renal and post renal acute renal injury; Patients with Glomerulonephritis; Patients requiring an immunosuppressive drug, including lupus; Patients taking omega-3 and corticosteroids in the last month; Pregnant; light-sensitive; malignant;

Intervention groups

Intervention group: Patients underwent intravenous laser radiation using infrared radiation. This method is non-thermal and non-toxic, using a continuous infrared beam or near infrared 600 nm with a power output of 5 mW. In this method, the laser light directly irradiates through a sterile disposable catheter. Two millimeters of optical fiber (200 nm in diameter and silicon dioxide) enter the vein and circulate in the circulation. This procedure is just like the injection of serum. Intravenous light red light, in this study with a power of 5 mW for 30 minutes. The intravenous laser is performed for 7 sessions per day. The NGAL level of urine and serum creatinine is measured and recorded before and after treatment.
Control group: Under Sham Laser.

Main outcome variables

NGAL level of urine; serum creatinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N30**
Registration date: **2018-02-10, 1396/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-10, 1396/11/21**
Update count: **0**

Registration date

2018-02-10, 1396/11/21

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Intravascular Laser Therapy on improvement of Acute Kidney Injury(AKI) with Urinary NGAL and Serum Cr

Public title

Effect of intravenous laser on acute renal injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute renal injury with intera renal causes in all classes R, I and F Complete satisfaction to participate in the study and completion of the therapeutic and follow up process

Exclusion criteria:

Post renal and prerenal acute renal injury Glomerulonephritis patients Patients who need an immunosuppressive drug, including lupus Patients taking omega-3 and corticosteroids in the last month Pregnant patients Light sensitive Malignant patient

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups according to randomized random numbers 1: 1 individual random sampling method. Patients and therapists are not aware of the type of study group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and therapists are not aware of the type of study group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2017-12-10, 1396/09/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.719

Health conditions studied

1

Description of health condition studied

acute renal impairment

ICD-10 code

N17

ICD-10 code description

acute renal impairment

Primary outcomes

1

Description

NGAL urine and serum creatinine

Timepoint

One occasion before assigning patients to treatment groups and one time at the end of treatment

Method of measurement

Laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients underwent intravenous laser radiation using infrared radiation. This method is non-thermal and non-toxic, using a continuous infrared beam or near infrared 600 nm with a power output of 5 mW. In this method, the laser light directly irradiates through a sterile disposable catheter. Two millimeters of optical fiber (200 nm in diameter and silicon dioxide) enter the vein and circulate in the circulation. This procedure is just like the injection of serum. Intravenous light red light, in this study with a power of 5 mW for 30 minutes. The intravenous laser is performed for 7 sessions per day.

Category
Treatment - Devices

2

Description
Control group: Under Sham Laser.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
Esmat Ghanei

Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2274 9221

Email
laser.cntr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Razaghi

Street address
Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2274 9221

Email
laser.cntr@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Esmat Ghanei

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Others

Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2274 9221

Email
laser.cntr@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Esmat Ghanei
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2274 9221
Email
laser.cntr@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Esmat Ghanei
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2274 9221
Email
laser.cntr@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable