

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Investigating the effects of intravenous laser therapy on the recovery process in patients with Acute Kidney Injury (AKI) using urinary NGAL

Protocol summary

Study aim

Determining the effect of intravenous laser therapy on the recovery process in patients with acute kidney injury using urinary NGAL

Design

A randomized, double-blind, sham-controlled clinical trial with a parallel group design of 40 patients

Settings and conduct

Participants will be given an explanation about the procedure and goals of the project, and written informed consent will be obtained from all patients. Patients will be assigned to two groups using random number generation. 1) Laser treatment group: Patients will undergo intravenous laser therapy for 30 minutes using continuous/pulsed light with a wavelength of 600-1100 nm and an output power of 1-500 mW. The laser light will be directly delivered into the bloodstream through a sterile disposable catheter. This treatment will be performed every other day for 7 sessions. 2) Control group: Patients will undergo sham laser treatment. Urine NGAL levels, GFR, and urine output will be measured and patients' demographics will be recorded. Laboratory tests including CBC, FBS, lipid and liver enzyme profiles, BUN, Cr, calcium, phosphorus, potassium and sodium will be measured. Evaluations will be performed before the treatment and at the end of the treatment period. 36-Item Short Form survey will be used to assess patients' health-related quality of life.

Participants/Inclusion and exclusion criteria

Patients with intra-renal acute kidney injury due to ATN (including toxic and ischemic interstitial nephritis)

Intervention groups

Control group: 7 sessions of treatment with sham laser
Intervention group: Intravenous laser treatment with infrared or near-infrared radiation (600-1100 nm, power=2 mW, 30 minutes) will be performed every other day for 7 sessions.

Main outcome variables

Urine NGAL levels, GFR, urine output

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N33**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **retrospective**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

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+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-07-23, 1398/05/01

Trial completion date

2019-07-23, 1398/05/01

Scientific title

Investigating the effects of intravenous laser therapy on the recovery process in patients with Acute Kidney Injury (AKI) using urinary NGAL

Public title

Investigating the effects of intravenous laser therapy on the recovery process in patients with Acute Kidney Injury (AKI) using urinary NGAL

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with intra-renal acute kidney injury (AKI) due to ATN (including toxic and ischemic interstitial nephritis)

Exclusion criteria:

Patients with pre-renal and post-renal acute kidney failure Patients with glomerulonephritis Patients who need immunosuppressive drugs such as patients with Lupus Patients who had been taking Omega-3 and corticosteroids within the past month Pregnant patients Patients with photosensitivity Patients with malignancy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into case and control groups based on randomly generated numbers. Group assignments will be concealed in sequentially numbered dark envelopes. The envelopes will be opened after the preliminary patient evaluation by a physician. Neither the patients nor the clinical evaluator will be aware of the group assignments.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient assessments will be performed before and after the treatments by a competent physician who is not affiliated with the research plan and is unaware of the treatment groups. Patients are not informed about the treatment groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University Ethics Committee in Biomedical Research

Street address

Shahid Beheshti University of medical sciences, Daneshjoo Blv, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

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 kidney injury

ICD-10 code

N17

ICD-10 code description

Acute kidney failure

Primary outcomes

1

Description

Urine Neutrophil gelatinase-associated lipocalin (NGAL)

Timepoint

Before the treatment and after the last session of laser therapy

Method of measurement

Measuring the NGAL levels in urine samples

2

Description

Glomerular filtration rate (GFR)

Timepoint

Before the treatment and after the last session of laser therapy

Method of measurement

Using the following equation: $(140 - \text{age}) \times (\text{weight}) \times (0.85 \text{ if female}) / 72 \times \text{Cr}$

3

Description

24-hour urine output

Timepoint

Before the treatment and after the last session of laser

therapy
Method of measurement
Urine sample

4

Description

Blood urea nitrogen (BUN)

Timepoint

Before the treatment and after the last session of laser therapy

Method of measurement

Blood sample

5

Description

Creatinine

Timepoint

Before the treatment and after the last session of laser therapy

Method of measurement

Blood sample

Secondary outcomes

1

Description

Patient's quality of life (mental and physical health)

Timepoint

Before the treatment and after the last session of laser therapy

Method of measurement

36-Item Short Form Survey

2

Description

Biochemical profile (Calcium, Phosphor, potassium, and sodium levels in blood, complete blood count, fasting blood sugar, total glycerides, total cholesterol, LDL, HDL, AST, ALT, ALKP)

Timepoint

Before the treatment and after the last session of laser therapy

Method of measurement

Patient's blood sample

Intervention groups

1

Description

Control group: 7 sessions of sham laser treatment

Category

Placebo

2

Description

Intravenous laser treatment with red or infrared radiation

(wavelength=600-1100 nm, power=2 mW, irradiation time=30 minutes) will be performed in seven sessions, every other day.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Sheida Malekian

Street address

Shohadaye Tajrish Hospital, Tajrish, Tehran

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sheida.mlkn@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

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

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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
Sheida Malekian
Position
Resident
Latest degree
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In the article and final report

When the data will become available and for how long

March 2020

To whom data/document is available

All people

Under which criteria data/document could be used

Journal

From where data/document is obtainable

Search

What processes are involved for a request to access data/document

Laser application in medical sciences research center

Comments