

Laser Doppler imaging as a tool in burn wound treatment

Submission date 06/09/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 07/11/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 07/02/2017	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Burns result in long stays in hospital and cause psychological problems. The main treatment of burns is early excision (removal) of injured tissue, which reduces inpatient stay and decreases the costs of treatment. There are many methods to assess burn wounds, but clinical examination of burn is still widely use. The aim of this study is to compare two different methods of examination of burned patients, clinical burn depth examination and Laser Doppler imaging, to estimate the impact of the two methods on length of stay in hospital and the costs of burns treatment.

Who can participate?

Patients age 18 to 75 with burns

What does the study involve?

Patients are randomly allocated to be undergo either clinical burn depth examination or laser Doppler imaging. Both groups also provide a biopsy (sample) of burned tissue under anaesthetic. The duration of the patients' stay in hospital and the cost of treatment are assessed in both groups.

What are the possible benefits and risks of participating?

Laser Doppler imaging may decrease the inpatient stay in hospital and cost of treatment. Clinical burn depth examination and Laser Doppler imaging are non-invasive investigations. There is a risk of wound bleeding after biopsy.

Where is the study run from?

Lithuanian University of Health Sciences (Lithuania)

When is the study starting and how long is it expected to run for?

May 2009 to May 2013

Who is funding the study?

Lithuanian University of Health Sciences (Lithuania)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Be 2-23

Study information

Scientific Title
Laser Doppler imaging as a tool in burn wound treatment: a prospective randomised trial

Acronym
LDI

Study objectives
Laser Doppler imaging is the first choice diagnostic approach of burned patients than clinical burn deep examination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kaunas Regional Ethics Committee, 11/04/2009, ref: BE 2-23

Study design
Prospective randomized controlled study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Plastic and reconstructive surgery

Interventions

There are two groups of patients:

1. Clinical burn depth examination group
2. Laser Doppler imaging group

Biopsy of burned tissue of both groups is carried out under local or intravenous anesthesia. LDI scan and CBDE are non invasive investigations

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Duration of patients' stay in hospital

Key secondary outcome(s))

1. Cost of treatment
2. Sensitivity and specificity of different burn examination
3. Perfusion parameters of burn tissue during LDI scan

Completion date

01/05/2013

Eligibility

Key inclusion criteria

1. Burned patients during 72 hours
2. Age 18 to 75 years
3. Agreement to participate in study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

1. Age > 75 years
2. Pregnant burned women
3. Mental disease of patients
4. Disagreement to participate in clinical study
5. Burned patients with critical condition of health who were treated in intensive care unite department

Date of first enrolment

01/05/2009

Date of final enrolment

01/05/2013

Locations

Countries of recruitment

Lithuania

Study participating centre

Lithuanian University of Health Sciences Kaunas Clinics

Kaunas

Lithuania

LT 50009

Sponsor information

Organisation

Lithuanian University of Health Sciences (Lithuania)

ROR

<https://ror.org/0069bkg23>

Funder(s)

Funder type

University/education

Funder Name

Lithuanian University of Health Sciences (Lithuania)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration