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Laser Doppler imaging as a tool in burn wound treatment

Submission date	Recruitment status	[ ] Prospectively registered
06/09/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/11/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/02/2017	Surgery	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Duration of patients' stay in hospital

Secondary outcome measures
1. Cost of treatment
2. Sensitivity and specificity of different burn examintion
3. Perfusion parameters of burn tissue during LDI scan

Overall study start date
01/05/2009

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
70 (35 in each group)

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
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Sponsor information

Organisation
Lithuanian University of Health Sciences (Lithuania)

Sponsor details
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Sponsor type
University/education

Website
http://www.kmuk.lt/

ROR
https://ror.org/0069bkg23

Funder(s)

Funder type
University/education

Funder Name
Lithuanian University of Health Sciences (Lithuania)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration