Energy metabolism of working muscles in patients after burn injury

Published: 08-10-2015
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Examine in vivo muscle energy metabolism in patients with burns, during rest, (prolonged) exercise and recovery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42597

Source
ToetsingOnline

Brief title
MetWork

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
burn wounds

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Dutch Burn Foundation

Intervention

Keyword: burn injury, Magnetic Resonance Spectroscopy, mitochondria, muscle function

Outcome measures

Primary outcome

In vivo intramuscular steady-state levels of inorganic phosphate (Pi), phoshocreatine (PCr), and pH at rest versus (prolonged) exercise, and the dynamics of Pi, PCr and pH recovery following exercise.

Secondary outcome

• Body composition

- body height (m)

- body weight (kg)

- waist circumference (cm)

• Muscle strength

- maximal isokinetic leg muscle strength (Newton), including Visual Analogue Scale (VAS) score for pain assessment during the test

- grip strength (Newton)

• Aerobic exercise capacity

- VO2max, FATMAX, peak work rate, peak heart rate, and percentage heart rate recovery after 1 and 2 minutes

- subjective fatigue and muscle ache score after CPET (scale 0-10)

• Prolonged exercise

- completion of 35 min upright bicycling bout at FATMAX (yes/no; if no,

#minutes)

- completion of 10 min supine bicycling bout at FATMAX in scanner (yes/no; if

no, #minutes)

- subjective fatigue and muscle ache score after each exercise bout (scale

0-10)

• Activity and fatigue

- Habitual Physical Activity Questionnaire

- Brief Fatigue Inventory

Study description

Background summary

Central to the process of optimizing burn care and rehabilitation is a comprehensive understanding of the pathophysiological response. There is evidence that impaired mitochondrial energy metabolism may play a major role in the pathophysiology and impaired muscle function documented in patients following major burn injury. Advanced research is required to further elucidate the role of skeletal muscle mitochondrial dysfunction in the pathophysiological response, particularly given the fact that mitochondria are sensitive to environmental and pharmacological interventions.

Study objective

Examine in vivo muscle energy metabolism in patients with burns, during rest, (prolonged) exercise and recovery.

Study design

Observational case control study

Intervention

not applicable

Study burden and risks

Patients will be asked to participate in two study sessions, with time between both sessions of 1-3 weeks.

• session I (site: Martini Hospital) scheduled in combination with a routine follow-up appointment at the Burn Centre of the Martini Hospital in Groningen.

In order to set the desired exercise workload of maximal individual rate of fat oxidation (FATMAX; typically ~40% VO2max) in session II, aerobic exercise capacity (VO2max) needs to be determined. In session 1 therefore, VO2max is assessed using a standard maximal cardiopulmonary exercise test (CPET; bicycle ergometry with respiratory gas analysis). Furthermore, body composition (body height, body weight, waist circumference), maximal isokinetic leg muscle strength (using a Cybex isokinetic dynamometer) and grip force (using the Citec hand-held dynamometer) will be assessed.

The assessments are safe and non-invasive and will take approximately 2 hours. Standard maximal cardiopulmonary exercise testing and isokinetic maximal strength assessment have been previously used in patients with major burns without adverse effects (St-Pierre, Choiniere et al. 1998, de Lateur, Magyar-Russell et al. 2007). Patients will be asked to abstain from heavy meals, caffeine and alcohol 2 hours prior to the test. After the assessments, patients will receive two short questionnaires about habitual physical activity and fatigue. These questionnaires can be filled in at home at any desired time between the two assessment sessions. This will take approximately 15 minutes.

• session II (site: Neuroimaging Magnetic Resonance Center, University Medical Center Groningen (UMCG)).

Working muscle metabolism: To determine energy and proton balance in the muscle during exercise and the kinetics of metabolic recovery following exercise, serial in vivo 31P MR spectra will be recorded non-invasively from the m. vastus lateralis of the right leg. To this end, patients will be asked to perform a 35 min upright bicycling exercise at FATMAX outside the MR scanner (exercise bout 1) followed by a 10 min supine bicycling exercise at FATMAX inside the MR scanner (exercise bout 2).
Application of 31P MRS in burn patients enables the non-invasive investigation of the impact of burn injury on the bioenergetics of working muscles in vivo. No adverse effects are expected. This and like protocols for in-magnet cycling has previously been included and approved in clinical investigations of metabolic myopathy patients protocols: 12-211/K (VLCAD; UMC Utrecht); NL41313.042.12 (MCAD; UMCG); METC 2014.492 (Acute Nutritional Ketosis in VLCAD; UMCG). The measurements in session II, including 31P MRS data collection, will take approximately 2 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged 18-65 years, admitted to the Martini Hospital Burn Center with burns covering 15% or more of total body surface area (TBSA).

Exclusion criteria

- only facial burns
- contraindications for MRI studies
- inability to perform bicycle exercise
- contra-indications for high intensity exercise testing
- known coronary artery disease, positive history for angina pectoris, or changes on ECG suggestive of previous ischaemia without a negative stress test

- intercurrent illness which may influence exercise tolerance (anaemia, musculoskeletal injury, or other undiagnosed illness under investigation)
- pre-existing insulin-dependent diabetes mellitus
- pregnancy or current breastfeeding, or females not taking the oral contraceptive pill
- any other cause which in the opinion of the investigators, may affect the volunteers ability to participate in the study
- insufficient proficiency in Dutch or English to the extent that clear communication is not possible
- loss of, or an inability to give informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2016
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	08-10-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53241.099.15
Other	OND1357794