

The effect of peri-operative anti-inflammatory treatment on postoperative muscle weakness and muscle fatigue in elderly elective surgery patients

Submission date 20/09/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/11/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/10/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Recently, studies have shown that elderly patients tend to suffer more from muscle weakness and muscle fatigue post-surgery than compared to younger patients. Also, we found evidence that muscle fatigue caused by inflammation is due to local processes (such as muscle atrophy and loss of contractibility), acting at the muscle itself. The aim of this study is to evaluate how different treatments work to reduce postoperative muscle weakness and muscle fatigue in elderly elective abdominal surgery patients.

Who can participate?

All elderly (male or female, aged >60 years) elective abdominal surgery patients are eligible.

What does the study involve?

Participants will be randomly allocated to either one of three drugs (including a drug which is a tumour necrosis factor-alpha (TNF- α) inhibitor) or a dummy drug (placebo), before during and after surgery.

What are the possible benefits and risks of participating?

We expect that the treatment will reduce the postoperative muscle weakness and fatigue. Patients will be excluded when contra-indications for the use of the study-medication exists. A recent study showed that TNF- α treatment did not increase the risk for surgical site infection.

Where is the study run from?

The leading centre is the Frailty in Aging research group of the Vrije Universiteit Brussel, in collaboration with the Universitair Ziekenhuis Brussel (University Hospital of the Vrije Universiteit Brussel), Belgium

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

October 2011 to September 2013.

Who is funding the study?

Frailty in Ageing research group of the Vrije Universiteit Brussel, in collaboration with the Universitair Ziekenhuis Brussel (University Hospital of the Vrije Universiteit Brussel), Belgium

Who is the main contact?

Dr Ivan Bautmans

ivan.bautmans@vub.ac.be

Contact information

Type(s)

Scientific

Contact name

Prof Ivan Bautmans

Contact details

Laarbeeklaan 103

Brussels

Belgium

1090

ivan.bautmans@vub.ac.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The effect of peri-operative anti-inflammatory treatment on postoperative muscle weakness and muscle fatigue in elderly elective surgery patients: a double blinded randomized placebo-controlled trial

Study objectives

Could Pharmacological interventions designed to prevent inflammation-induced structural changes in the skeletal muscle reduce postoperative muscle weakness and muscle fatigue in elderly elective abdominal surgery patients?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Brussels University Hospital Medical Ethical Committee (Universitair Ziekenhuis Brussel)

Study design

Double blinded randomised placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Post-operative muscle weakness, fatigue and inflammation

Interventions

Three different pharmacological interventions, each counter-acting different steps of the inflammation-induced proteolytic pathway in skeletal muscle, will be compared to placebo control:

1. Tumor necrosis factor-alpha (TNF-a) inhibitor [50mg Etanercept by subcutaneous (SC) injection 1 day preoperative, N=25)
2. Calpain inhibitor (16mg Molsidomine daily by mouth (per os), starting 1 day preoperative until 1 week postoperative, N=25)
3. Nuclear factor kappa-light-chain-enhancer of activated B cells (NF-eB) downregulator (267mg Fenofibrate daily, starting 1 day preoperative until 1 week postoperative N=25)
4. Placebo control (N=25)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Muscle performance: Maximal handgrip strength, muscle fatigue resistance and grip work will be assessed one day before surgery, and 2, 4, 8 and 30 days post-surgery
2. Self-perceived fatigue and pain: self-perceived fatigue (Fatigue subscale of the Profile of Mood State) and pain (Visual Analogue Scale) will be assessed one day before surgery, and 2, 4, 8 and 30 days post-surgery
3. Inflammation: circulating levels of pro- and anti-inflammatory cytokines and their intra-cellular

gene expression in Peripheral Mononuclear Blood Cells. Overnight fasting serum samples will be collected from the non-dominant arm at one day before surgery, and 2, 4, 8 and 30 days post-surgery.

Secondary outcome measures

Occurrence of adverse reactions and postoperative complications:

All participants will be questioned and monitored for adverse reactions (potentially related to the study medication, i.e. allergies, headache, hypotension) at day 2, 4, 8 and 30 post-surgery.

Occurrence of postoperative complications will be extracted from the patients medical record.

Overall study start date

01/10/2011

Completion date

01/10/2013

Eligibility

Key inclusion criteria

All elderly (male or female, aged > 60 years) elective abdominal surgery patients

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

N=100 (N=25 per treatment arm)

Key exclusion criteria

1. Unavailable one day before the surgical intervention
2. Presenting important inflammation preoperatively C-reactive protein (CRP)>10mg/L
3. Unable to understand or execute the test instructions due to cognitive impairment mini mental state examination (MMSE<23 / 30) and/or physical disability
4. Already using selective tumor necrosis factor (TNF)-alpha inhibitors, nitric oxide donors, fibrates, non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids or when contra-indications for the use of one of these products exist

Date of first enrolment

01/10/2011

Date of final enrolment

01/10/2013

Locations

Countries of recruitment

Belgium

Study participating centre

Laarbeeklaan 103

Brussels

Belgium

1090

Sponsor information

Organisation

Vrije University Brussels [Vrije Universiteit Brussel] (Belgium)

Sponsor details

Frailty in Ageing Research Department

Laarbeeklaan 103

Brussels

Belgium

1090

ivan.bautmans@vub.ac.be

Sponsor type

University/education

Website

<http://www.vub.ac.be/FRIA>

ROR

<https://ror.org/006e5kg04>

Funder(s)

Funder type

University/education

Funder Name

University of Brussels (Belgium)

Funder Name

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/03/2010		Yes	No