

# Improving post-operative outcomes in older vascular surgical patients

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<b>Registration date</b> 19/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/12/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The rate of older people having operations is increasing faster than the rate of population ageing. Surgery has survival and symptomatic benefits for older people. Despite this older people are more likely to suffer from complications after surgery than younger people. Medical conditions and 'geriatric syndromes' (e.g. memory problems, delirium/acute confusion, frailty) are common in older people. These increase the risk of complications after surgery. Older vascular surgical patients are a particularly high risk group. They commonly have several vascular risk factors (e.g. high blood pressure, diabetes, smoking, high cholesterol, heart disease, stroke etc). These increase risk of the geriatric syndromes listed. The current NHS processes for assessing older patients before surgery do not involve proactive examination for geriatric syndromes. Because these syndromes are not identified they are not managed or optimised. Geriatricians use a method of assessing and treating older patients called Comprehensive Geriatric Assessment (CGA). CGA identifies issues (whether already diagnosed or previously unidentified) and employs a long-term management plan. Issues range from medical problems to social issues or functional limitations. Within medical and community-dwelling older people CGA improves survival and function. We know less about the impact of CGA within older surgical patients. This study will investigate whether preoperative CGA in older vascular surgical patients focussing specifically on memory problems, risk of delirium after surgery and frailty will:

1. Reduce length of hospital stay
2. Improve rates of identification of memory impairment and onward referral to memory services
3. Improve rates of identification/modification of delirium risk factors before the operation to reduce the incidence of delirium after the operation
4. Improve explanation/education to patients/relatives about delirium which may reduce the related distress
5. Improve identification of frailty and optimisation of aspects of frailty (e.g. poor nutrition/low mood)

The study will investigate what works and why and examine whether CGA provides value for money when compared to standard care for older vascular surgical patients.

### Who can participate?

Patients aged 65 and over listed for an operation (endovascular/open thoracoabdominal aortic aneurysm repair or lower limb arterial bypass surgery/debridement) under the care of the vascular surgeons at Guy's and St Thomas' NHS Foundation Trust.

### What does the study involve?

Participants are randomly allocated to the treatment group or the control group. The treatment group are given a thorough assessment by a healthcare team specialising in preparing older people for surgery. This usually involves a single visit only to a hospital clinic. The team consists of doctors, nurses, occupational therapists and social workers. As part of a detailed assessment the following areas are covered:

1. Cognitive or memory assessment
2. Assessment for risk of delirium (this is the chance that patients may be confused or drowsy after an operation as a result of a condition called delirium)
3. Frailty assessment

The control group are treated in the usual manner, which is routine care from a nurse in a pre-assessment clinic possibly involving the patient's GP and other services. This also usually only involves a single visit to a different hospital clinic.

### What are the possible benefits and risks of participating?

The possible benefits include:

1. A more in-depth assessment which may identify previously unmet physical or social needs for the patients
2. Fuller discussion of the potential problems which may occur after an operation with the opportunity to ask questions about these
3. Treatment of conditions which put older patients at risk after surgery - this may lead to less problems after an operation
4. A potentially shorter length of hospital stay for patients

There are no risks of participating in this study. No experimental medicines will be used in either group. The operation will not be affected at all by taking part in the study.

### Where is the study run from?

Guy's and St Thomas' NHS Foundation Trust (UK)

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

October 2012 to July 2013

### Who is funding the study?

This study is funded by a Joint British Geriatrics Society & Research into Ageing Fund-Age UK Clinical Fellowship in Ageing Research (UK)

### Who is the main contact?

Dr Danielle Harari

## Contact information

### Type(s)

Scientific

### Contact name

Dr Danielle Harari

**Contact details**

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

13260

**Study information****Scientific Title**

Evaluating the impact of preoperative Comprehensive Geriatric Assessment (CGA) to improve postoperative outcomes in older vascular surgical patients

**Study objectives**

Older patients undergoing surgical procedures are at higher risk of poor postoperative outcomes than younger patients. Age-related syndromes including cognitive impairment, postoperative delirium (POD) and frailty adversely impact postoperative outcomes and increase length of stay (LOS). Vascular risk factors are common in the vascular surgical population. These risk factors put older vascular surgical patients at high risk of cognitive impairment, POD and frailty.

We conducted an observational study in patients age 65+ undergoing vascular surgery. We found high levels of undiagnosed cognitive impairment and frailty and a significant incidence of POD. Current preoperative assessment does not identify these issues.

This randomised controlled trial will examine the impact of preoperative comprehensive geriatric assessment (CGA) on the following outcomes;

1. Length of stay (days)
2. Increase in preoperative identification rates of:
  - 2.1. Cognitive impairment
  - 2.2. Delirium risk
  - 2.3. Frailty
3. Increase in:
  - 3.1. % patients referred to dementia services
  - 3.2. % patients in whom delirium risk is optimised
  - 3.3. % frail patients receiving multidisciplinary input

#### 4. Reduction in postoperative

##### 4.1. Delirium

##### 4.2. Patient/relative distress related to delirium

#### 5. Feasibility and process measures describing how a targeted CGA intervention can be embedded within vascular surgery

The study will be conducted at Guy's and St Thomas' Hospital, London. Patients aged 65+ undergoing aortic and lower limb arterial surgery or amputation will be recruited from vascular surgical outpatients. Following the consent process patients will be randomised to either control group (standard preoperative care) or intervention group (pre-operative comprehensive geriatric assessment and optimisation). The intervention clinic is in place of the usual nurse-led preoperative assessment (thus minimising hospital attendances).

#### **Ethics approval required**

Old ethics approval format

#### **Ethics approval(s)**

South East Research Ethics Committee, 18/05/2012, ref: 12/LO/0655

#### **Study design**

Randomised interventional trial

#### **Primary study design**

Interventional

#### **Secondary study design**

Randomised controlled trial

#### **Study setting(s)**

Hospital

#### **Study type(s)**

Prevention

#### **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**

Age and ageing, surgery

#### **Interventions**

Treatment arm - single clinic visit for Comprehensive Geriatric Assessment and Optimisation  
Control arm - single routine preoperative assessment clinic appointment

Follow up duration for both arms - time spent in hospital with 3 month telephone call follow up after discharge.

#### **Intervention Type**

Procedure/Surgery

**Phase**

Not Applicable

**Primary outcome measure**

Length of hospital stay (LOS) measured at time of hospital discharge

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

30/10/2012

**Completion date**

30/07/2013

## Eligibility

**Key inclusion criteria**

1. Aged 65 years and over
2. Scheduled to undergo aortic or lower limb arterial surgery, debridement or amputation within the next 4 months
3. Male and female

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

UK Sample Size: 180

**Key exclusion criteria**

1. Patients admitted directly to the ward from surgical clinic for emergency or very urgent surgery
2. Capacious patients who decline to attend pre-operative assessment clinic
3. Patients who decline to consent to participation in the study

**Date of first enrolment**

01/11/2012

**Date of final enrolment**

30/07/2013

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St Thomas's Hospital**

London

United Kingdom

SE1 7EH

## **Sponsor information**

**Organisation**

Guy's and St. Thomas' NHS Foundation Trust (UK)

**Sponsor details**

Thomas Guy House

Lambeth Palace Road

London

England

United Kingdom

SE1 7EH

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.guysandstthomas.nhs.uk/>

**ROR**

<https://ror.org/00j161312>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

British Geriatrics Society

**Alternative Name(s)**

BGS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United Kingdom

**Funder Name**

Age UK

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	01/05/2017		Yes	No