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Improving post-operative outcomes in older vascular surgical patients

Submission date	Recruitment status	[_] Prospectively registered
19/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/11/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/12/2017	Surgery	

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

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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. Capacitous 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?
Results article	results	01/05/2017		Yes	No