

Effect of increasing low serum hemoglobin level on functional recovery after hip fracture surgery in the elderly. A prospective randomized clinical trial.

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To assess whether increasing low hemoglobin levels to near normal accelerate functional recovery and shorten the revalidation period after hip fracture surgery in the elderly.

Ethical review	Approved WMO
Status	Pending
Health condition type	Haematological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32131

Source

ToetsingOnline

Brief title

HERO (= HEMoglobin and functional Recovery in Older patients)

Condition

- Haematological disorders NEC
- Fractures
- Bone and joint therapeutic procedures

Synonym

anemia in elderly patients with hip fracture after surgery

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: elderly, hemoglobin, hipfracture surgery, transfusion

Outcome measures

Primary outcome

The primary outcome measure is the number of days of admittance in the hospital counted from the first day of the hip surgery until the day of discharge or the day that the patient for medical reasons could have been discharged but due to external factors, like *no help at home* or no rehabilitation space available, has to stay in the hospital (the so called *wrong bed patient*). The day of discharge is determined by the functional performance of the patient and the ability to perform (almost) independency for daily activities.

Secondary outcome

Secondary outcomes are the following functional measurements:

In hospital mortality, place of residence after hospital discharge, and in hospital complications like delirium, infections or cardiovascular events.

Study description

Background summary

Hip fractures are a main cause of morbidity and mortality in the elderly population, and numbers are expected to increase in the future. Functional recovery after hip repair in elderly subjects is related to long-term mortality and independence. One potential method to improve post-operative functional recovery is to treat peri-operative anemia. There is no consistent evidence on

the relation of the post operative hemoglobin levels and functional outcome after hip repair. Red blood cell transfusions are frequently necessary in the usual post-operative care after hip surgery, because this type of surgery is associated with considerable blood loss. Most hospitals in the Netherlands use restrictive transfusion policy because of the potential risks associated with allogenic red blood cell transfusions. This general accepted policy contrasts with our clinical observation among 317 patients who underwent hip fracture surgery and showed significantly longer hospital stay when having lower post-operative hemoglobin values. With incidence rates of less than 0.1 % for acute lung injury and of less than 0.01% for viral and bacterial infections, the risks associated with red blood cell transfusions is relative low.

Study objective

To assess whether increasing low hemoglobin levels to near normal accelerate functional recovery and shorten the revalidation period after hip fracture surgery in the elderly.

Study design

This is a prospective randomized clinical trial.

The study will be performed in elderly patients undergoing hip surgery for emergency reason. The patients must be at least 65 years. The transfusion threshold group will consist of (minimal) 200 subjects and the restricted transfusion group (= *usual care group*) will consist of (minimal) 200 patients

Intervention

In group A, the transfusion threshold group, the patients will receive as much additional blood as needed to keep the hemoglobin level above 7.5 mmol/L (= 12 gr/dL). So women will be transfused till the normal hemoglobin level and in men to near normal hemoglobin levels have been reached. Leukocyte depleted red blood cell transfusion will be used.

Study burden and risks

No more risks are associated with participation than with usual patient care after hip fracture surgery.

Contacts

Public

Leids Universitair Medisch Centrum

albinusdreef 2
2300RC Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

albinusdreef 2
2300RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

age 65 years and older with hipfracture surgery

Exclusion criteria

multi trauma patient or hemorrhagic shock

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL22437.058.08