Dynamic Locking Blade Plate (DLBP) versus Dynamic Hip Screw (DHS) for displaced femoral neck fractures in patients 65 years of age and younger. A multicentre randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON52560

Source
ToetsingOnline

Brief title
DEFENDD study

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
Femoral neck fracture. Hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Deventer Ziekenhuis.

Intervention

Keyword: DHS, Displaced, DLBP, Femoral neck fracture

Outcome measures

Primary outcome

Incidence of revision surgery after fixation of a displaced FNF treated with

DLBP or DHS due to non-union, AVN or cut out of the implant.

Secondary outcome

Incidence of avascular necrosis

Incidence of non-union

Incidence of implant related complications.

Post-operative complications

Rate of elective implant removal after union

Functional outcome

Operation time

Costs

Health related quality of life.

Study description

Background summary

In 1990 an estimated 1.66 million patients sustained a hip fracture worldwide. This number has increased over time and is estimated to be 6 million in 2050 worldwide. Despite these numbers the optimal treatment of hip fractures is

still under debate. Especially the treatment of displaced femoral neck fractures (FNF) differs worldwide. A general consensus is that young patients (up to 65 years of age) should be treated with fracture reduction and internal fixation. Nowadays the most commonly used implants are multiple cannulated parallel screws and the dynamic hip screw (DHS). The DHS has a small advantage over multiple parallel screws in displaced FNF. Despite the frequent use of these implants the failure rate is still high, with a non-union rate of 30-33% and an incidence of avascular necrosis of 10-16%. The reoperation rate lies between the 18-48%. The Dynamic Locking Blade Plate (DLBP), otherwise called *The Gannet*, is specifically designed for the surgical fixation of intracapsular hip fractures. The characteristics of the DLBP are its low implant volume, rotational stability, angular stability and its simple instrumentation and surgical technique. In a prospective multicenter cohort study in the Netherlands 172 patients with undisplaced FNF were treated with the DLBP. The results of this study showed a failure rate of 4%. Another recent prospective cohort of 114 patients of 60 years and younger with displaced FNF demonstrated a DLBP related failure rate 13.2%.

The primary objective of this trial is to test if these favorable results with the DLBP can be upheld in a multicenter randomized controlled trial with patients up to 65 years with a displaced FNF. We hypothesize that the DLBP is superior compared to the DHS in terms of revision surgery, union rate, AVN, implant related failure, as well as functional outcome.

Study objective

The primary objective of this trial is to test if these favorable results with the DLBP can be upheld in a multicenter randomized controlled trial with patients up to 65 years with a displaced FNF. We hypothesize that the DLBP is superior compared to the DHS in terms of revision surgery, union rate, AVN, implant related failure, as well as functional outcome.

Study design

This is a multicenter unblinded randomized controlled trial with a superiority design comparing two surgical procedures.

Intervention

One group will be treated with the Dynamic Locking Blade Plate. The other group will be treated with Dynamic Hip screw (control group).

Study burden and risks

The additional burden for patients by participating in this study is minor. The patients will be asked at five times to complete a questionnaire via internet

or by post. The patients will visit the outpatient clinics three times after discharge. At least two of these visits will be routine follow-up visits after treatment. Therefore this is potentially one extra follow up visit for other reasons than the routine follow-up visits. The treatment will not differ from the standard care of femoral neck fractures. Both implants that are used in this study are CE-registered devices and commonly used in multiple hospitals in the Netherlands and abroad.

Contacts

Public
Deventer Ziekenhuis

Nico Bolkesteinlaan 75
Deventer 7416 SE
NL
Scientific
Deventer Ziekenhuis

Nico Bolkesteinlaan 75
Deventer 7416 SE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• 18- 65 years
• Displaced Femoral Neck Fracture (Garden type III or IV) 14
• Written informed consent

Exclusion criteria

Patients with:
• Pathological fracture.
• Ipsilateral or contralateral fractures of the lower extremity.
• Patients with an Injury Severity Score (ISS) of >=16.
• Local infection or inflammation.
• Symptomatic arthritis, diagnosed by a rheumatologist.
• Symptomatic osteoarthritis or radiographic osteoarthritis grade III or IV. 15
• Previous surgery to the ipsilateral hip.
• Inadequate tissue coverage.
• Morbid obesity (BMI >= 35).
• Patients who are wheelchair-bound.
• Patients who were, at the time of trauma, admitted to a nursing home.
• Patients who are not mentally competent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-10-2019
Enrollment:	266
Type:	Actual

Medical products/devices used

Generic name:	Dynamic Locking Blade Plate
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-08-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-10-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-06-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-02-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL63529.075.18