Complications and survival of primary and conversion Total Hip Arthroplasties after femoral neck fractures: A comparison of two procedures

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28439

Source
Nationaal Trial Register

Brief title
cTHA versus pTHA

Health condition

Failed internal fixation after FFN converted to THA versus primary THA after FFN

Sponsors and support

Primary sponsor: Rijnstate Hospital Arnhem
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The main study outcome is the complication rate of: postoperative dislocations,

postoperative infections, periprosthetic fractures, prosthetic instability, postoperative bleedings, postoperative cardiorespiratory complications and mortality.

Secondary outcome

The secondary study outcome is the survival of the pTHA implants and cTHA implants after a failed DHS or multiple (cannulated) screw fixation.

Study description

Background summary

For patients with an intracapsular fracture of the femoral neck (FFN), surgical treatment options are femoral head sparing techniques (Dynamic Hip Screw (DHS), three cannulated screws) or (hemi)arthroplasty. The options for surgical technique is often dictated by the patients age, since arthroplasties tend to survive for about 15-20 years. The femoral head sparing technique is preferred in relatively young patients (< 70 years) with an undisplaced FFN. Possible complications of headsparing techniques are avascular necrosis (AVN), non-union, malunion or (in the longer term) posttraumatic osteoarthritis and may result in a conversion to Total Hip Arthroplasty (cTHA). Evidence of complication rates and survival rates of the cTHA compared to primary Total Hip Arthroplasty (pTHA) after FFN is lacking. Registries collect data about all THA implantations, but they do not register all the postoperative dislocations, infections and intra-operative periprosthetic fractures after THA. However, Dutch hospitals do register these complications. Therefore, this study may give new insight into the frequency of these relevant clinical endpoints and differences in short term survival between pTHA and cTHA after FFN. It is hypothesised that pTHA after FFN results in a significant lower rate of postoperative complications and a better short term survival. The identification of the dislocation rate in pTHA and cTHA after FFN may assist clinicians to determine the need for dual mobility cups in cases of increased dislocations in these specific patient populations and the appropriate provision of information to patients itself.
The aim of this study is to evaluate the complication rate and short term survival of the THA implant in patients treated with pTHA after a FFN compared to patients treated with cTHA whose internal fixation failed after a FFN.

Study objective

pTHA showed significant less complications postoperatively

Study design

1 year

Contacts

Public
Rijnstate Arnhem
Eelco van Leent

0620096005
Scientific
Rijnstate Arnhem
Eelco van Leent

0620096005

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria:
• Age ≥ 18
• Having had a femoral neck fracture
• Having been treated with a pTHA or DHS or multiple cannulated screw fixation which subsequently failed and which was then converted to THA (cTHA).

Exclusion criteria

All patients with an:
• Ipsilateral Intramedullary femoral nail
• Ipsilateral Hemiartroplasty
• Polytrauma
• Ipsilateral pathological fracture
• Neoplasma or metastatic disease
• Contralateral hip fracture
will be excluded from participation in this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-03-2020
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	10-03-2020
Application type:	First submission

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
NTR-new	NL8452
Other	METC Radboudumc : 2020-6321

Study results