# Bone Impaction grafting vs standard fixationtechnique of the acetabular cup in total hip arthroplasty in patients under 60.

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HypothesisThe alternative hypothesis of this study is patient satisfaction on HOOS score that BIG technique is not inferior to the golden standard 1 year post-surgery in patients younger than 60 years with osteoarthritis of the hip wherefor total...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Joint disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36900

**Source**
ToetsingOnline

**Brief title**
BIG-trial

### Condition

- Joint disorders

**Synonym**
degenerative hip disease, osteoarthritis of the hip

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** geen

## Intervention

**Keyword:** Bone impaction grafting, Satisfaction, Standard fixation technique, Total hip arthroplasty

## Outcome measures

### Primary outcome

Patient satisfaction with HOOS-functioning in daily live subscale 1 year

post-surgery is primairy outcome. The definition of succes (non-inferiority)

for the individual patient is as follows: a clinical non-relevant difference is

defined as 9 points or less on the HOOS functioning in daily life subscale.

### Secondary outcome

Besides the other 4 HOOS subscales and the HOOS total score, the following

secundary outcomes will be used to evaluate effectivity of both

fixationtechniques:

- VAS pain and VAS satisfaction

- SF 36

- Clinical data: Bloodloss, surgery time, length of hospital stay

- Radiological

- X-ray: version and inclination cup

- Complications: bleeding, infection, dislocation, meralgia paraesthetica,

venous thromboembolism and loosening

Simultanously course in time of HOOS, VAS, SF 36 will be analyzed.

# Study description

## Background summary

Around 1950 the total hip arthroplasty is placed as a treatment for debilitating osteoarthritis of the hip. In The Netherlands this surgery is done around 25.000 times a year. Most important complications are dislocation, infection, thrombo-embolisms and loosening. Indication. choice of prosthesis, approach and fixation of components should carefully be considered in placing THP. In the Isala Clinics approximately 100 patients of 60 years and younger receive a THP. 70% is reversed hybrid and in 30% both components are placed with bone cement.

Normal fixation technique
For fixation of the acetabular cup can be chosen for the cemented and uncemented fixation technique. There are no high qualified studies which prove superiority of one of both methods. In Europe mainly the cemented technique is used while in the United States and Australia the uncemented technique is the standard. In a recent review of Clement et al. no difference is found between the cemented and uncemented cup in elderly patients. In the younger population also no difference is found in overall survival between cemented versus uncemented cup.

Bone Impaction Grafting (BIG) technique
The first description of the BIG technique is done bij Hasting et al. in de mid seventies where the technique was used in patients with protrusio acetabuli as a result of rheumatoid arthritis. In 1979 the technique is improved bij Slooff et al. by creating a contained defect and impaction with autogene or allogene trabecular bone before placing the cup.Step by step this means that the acetabulum is prepared using the standard technique. Defect are filled with bone graft. There can be chosen for a metal mesh for containing the defect. Next particles of trabecular bone are impacted with a pusher and hammer. De thickness of impacted bone should be at least 5 mm. In the end, the cup can be cemented into the created acetabulum. The results of the BIG technique in young patients with regard to overall survival of the cup are equal or superior to the survival of the cup with the BIG technique in patients of any age.

## Study objective

Hypothesis
The alternative hypothesis of this study is patient satisfaction on HOOS score that BIG technique is not inferior to the golden standard 1 year post-surgery in patients younger than 60 years with osteoarthritis of the hip wherefor total hip arthroplasty.

Primairy goal

To demonstrate that patient satisfaction with the BIG technique is equal or better than the standard fixation technique of the cup in the acetabulum in patients younger than 60 years which have a THA.

Secundairy goals
- To demonstrate that there is a difference in clinical and functional outcomescores between BIG technique and standard fixation technique in patients under 60 years with THA.
- To demonstrate that there is a difference in radiological parameters between BIG technique and standard fixation technique in patients under 60 years with THA.
- To demonstrate that there is a difference in number of complications between BIG technique and standard fixation technique in patients under 60 years with THA.

**Study design**

It concerns a single center, triple blind, randomized controlled trial where the BIG technique is compared to the standard fixation technique with regard to fixation of the cup in the acetabulum. Patients will be followed during 10 years after surgery at the outpatient clinic at the standard control moments. Questionnairies will be part of the control. The controlmoments are based on regular control moments as stated by the Dutch Orthopedic Society (NOV). Both groups will be prospectively followed. Per surgeon will be randomized between BIG and non-BIG.

**Intervention**

Surgery will be conducted by the orthopedic dept of the Isala Clinics Zwolle. A total of 132 patients will have THA of which 66 will have a standard fixation technique and 66 will have BIG technique. Both surgeons will do 33 standard and 33 BIG techniques.

For surgery the next components will be used:
Stem: BiMetric (Biomet)
Cup: FAL (LINK)
Head: Biolox ceramic

Both groups will have the same bloodsupply- and painmanagement. Post-operative rehabilitation will take place according to a standardized protocol for THP with a posterolateral approach and is the same for both groups.Every patient will receive systemic profylactic antibiotics (cefazolin 2gr intravenous) and thromboprofylaxis (fondaparinux 0.3mg SC till 5 weeks post-surgery)

**Study burden and risks**

The BIG technique is a worldwide common accepted technique. The peroperative and post-surgery risks are no different than the standard fixation technique. A disadvantage is that surgery time may be a bit longer. Questionairries will be taken during the outpatient clinic visits.

## Contacts

**Public**
Isala Klinieken

Groot Weezenland 20
Zwolle 8011 JW
NL
**Scientific**
Isala Klinieken

Groot Weezenland 20
Zwolle 8011 JW
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

1. Signed informed consent
2. Age between 18 and 60 years
3. Mentally competent men and women with debilitating osteoarthritis of the hip indicated for a total hip arthroplasty

### Exclusion criteria

1. BMI > 35
2. Previous ipsilateral hipsurgery
3. Contralateral debilitating osteoarthritis of the hip
4. Acetabular defects wherefore BIG indicated:
- AAOS type 1-5 defect
- Acetabular fracture with more than 2 mm dislocation
- DDH with CE angle < 25 degrees
- Protrusio acetabuli
- M. Perthes with deformed acetabulum
- Slipped Capital Femoral Epiphysis (SCFE)
- Degenerative cyst >2 cm
5. Rheumatoïd Arthritis (RA)
6. Hip dislocation
7. Malignancy
8. Standard contraindications, as prevailing for elective total hip arthroplasty (pregnancy, infection and severe comorbidity of pulmonary, cardiac or metabolic nature)

## 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

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-12-2012 |
| Enrollment: | 132 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 29-10-2012 |
| Application type: | First submission |
| Review commission: | METC Isala Klinieken (Zwolle) |

# 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 | NL40767.075.12 |

# Study results

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|---|---|
| Date completed: | 03-09-2020 |
| Results posted: | 23-08-2021 |
| Actual enrolment: | 131 |

**First publication**
19-08-2021