

LEAK study

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26417

Source

Nationaal Trial Register

Brief title

LEAK

Health condition

totale knie arthroplastiek, totale heup arthroplastiek, wond lekkage, prothese infectie, revisie chirurgie voor infectie.

total knee arthroplasty; total hip arthroplasty; wound leakage; prosthetic joint infection; debridement; revision surgery for infection

Sponsors and support

Primary sponsor: UMCG

Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

What is the effectiveness of early intervention (DAIR day 10) versus usual care (nonsurgical treatment) in patients with

persistent wound leakage? Primary endpoint will be revision surgery for PJI up to one year.

Secondary outcome

What is the cost effectiveness and cost utility of early intervention (DAIR day 10) versus usual care (nonsurgical treatment) in

patients with persistent wound leakage? Primary endpoint will be revision surgery for PJI up to one year.

What is the impact of early intervention (DAIR day 10) compared to usual care (nonsurgical treatment) on disease-specific and general health-related quality of life at one year?

Study description

Background summary

RATIONALE:

Persistent wound leakage after primary Total Knee or Hip Arthroplasty (TKA/THA) is associated with Prosthetic Joint Infection (PJI). More than 50,000 TKA/THA are performed yearly in the Netherlands. PJI is a serious complication with major implications for a patient's quality of life and costs are high ($\pm$ € 30,000). Clinical practice for the treatment of persistent wound leakage varies considerably, with both nonsurgical or surgical treatment options. The dilemma is that not all postoperative prolonged wound leakages are a proxy for PJI. So far literature shows no evidence for the superiority of either treatment.

OBJECTIVE RESEARCHQUESTION:

To determine clinical and cost effectiveness and impact on quality of life of early intervention (DAIR on day 10) versus usual care (nonsurgical treatment) in patients with persistent wound leakage.

HYPOTHESIS:

Early intervention reduces 50% revision surgery for PJI =1 year compared to usual care.

STUDY DESIGN:

A randomized controlled trial comparing two clinical pathways.

STUDY POPULATION/DATASETS:

Patients aged 18 or older who have undergone a TKA/THA and experience persistent wound leakage at day 9.

INTERVENTION:

Surgical treatment: DAIR on day 10, cleaning of wound and prosthesis, cultures and AB.

USUAL CARE/COMPARISON:

Nonsurgical treatment: bed rest, stop exercise, pressure bandage.

OUTCOME MEASURES:

Primary outcome: reduction in revision surgeries for PJI =1 year after TKA/THA. Secondary outcomes: number of DAIRs, costs, and disease-specific and general health-related quality of life.

SAMPLE SIZE CALCULATION/DATA ANALYSIS:

The expected reduction rate of revision surgery for PJI as a result of early intervention is estimated at 50%. The numbers needed from inclusion are 194 in each arm, compensating with 20% for lost to follow-up (alpha 0.05, power 80% one-sided).

COST-EFFECTIVENESS ANALYSIS/BUDGET IMPACT ANALYSIS:

Cost-effectiveness analysis (costs per prevented revision surgery for PJI), cost-utility analysis from a societal perspective (costs per QALY) and a probabilistic Budget Impact Analysis will be conducted.

TIME SCHEDULE:

The LEAK study is prepared between 1-9 and 31-12-16; patients inclusion will be from 1-1-17 to 1-1-18 with a maximum extension of six months. Data analysis will finish within 6 months of completion of the last follow-up patient. Total study length is 3 years.

Study objective

Surgical treatment (DAIR on day 10) will result in a 50% reduction rate of revision for PJI up to one year after primary TKA/THA compared to nonsurgical treatment. Consequently surgical treatment is more (cost) effective compared to nonsurgical treatment. DAIR on day 10 will result in improvement of disease-specific and general health-related quality of life compared to nonsurgical treatment.

Study design

T0= at time of inclusion

T1= at 1 year followup

Intervention

non-surgical and surgical treatment of persistent wound leakage

Contacts

Public

UMCG

P.C. Jutte
Postbus 30.001

Groningen 9700RB
The Netherlands
T: 0503612802 |

Scientific

UMCG

P.C. Jutte
Postbus 30.001

Groningen 9700RB
The Netherlands
T: 0503612802 |

Eligibility criteria

Inclusion criteria

Patients aged 18 or older who have undergone a TKA/THA and experience persistent wound leakage at day 9.

Exclusion criteria

- Mental or physical disability to fulfill study requirements.

- Insufficient command of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2017
Enrollment:	388
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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

NTR-new

NTR-old

Other

ID

NL5805

NTR5960

ZonMW : 843004101

Study results

Summary results

n/a