LEAK study

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26417

Bron
Nationaal Trial Register

Verkorte titel
LEAK

Aandoening

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

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 (± € 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.

Doel van het onderzoek

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.

Onderzoeksopzet

T0= at time of inclusion

T1= at 1 year followup

Onderzoeksproduct en/of interventie

non-surgical and surgical treatment of persistent wound leakage

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Mental or physical disability to fulfill study requirements.

- Insufficient command of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	388
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5805
NTR-old	NTR5960
Ander register	ZonMW : 843004101

Resultaten

Samenvatting resultaten
n/a