Total Ankle Replacement using Guides, Expert versus Trainee

Published: 07-06-2023
Last updated: 02-12-2024

Primary Objective: To compare the post-operative alignment accuracy of PSI PROPHECY*TAR between a beginning (group A) and an experienced orthopedic surgeon (group B).Secondary Objective: To compare the operative time, complications, and patient-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON56252

Source
ToetsingOnline

Brief title
TARGET

Condition

- Joint disorders

Synonym
joint wear, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: subsidie Noordwest Orthopedisch Centrum

Intervention

Keyword: Learning curve, Patient-specific instrumentation (PSI), Total ankle replacement (TAR)

Outcome measures

Primary outcome

The difference in TAR component accuracy between the preoperative and 2-year postoperative model based on CT scans.

Secondary outcome

Abandonment of PSI per-operative, percentage of accurately aligned components, percentage of accurately predicted implant size (both talar rand tibia components), patient-reported outcome measures (PROM), and complication and revision rate.

Study description

Background summary

Patient Specific Instrumentation (PSI) is thought to quicken the process by shortening the operation time and improve alignment. Studies about the learning curve of PSI for total ankle replacement (TAR) are lacking because it was only introduced in 2014 (PROPHECY guidelines; Stryker). Our goal is to extend the availability of TAR in all Dutch patients with end-stage osteoarthritis. We hypothesize that PSI can give a (beginning) surgeon new to TAR an advantage because PSI facilitates the complex TAR procedure.

Study objective

Primary Objective:
To compare the post-operative alignment accuracy of PSI PROPHECY*TAR between a beginning (group A) and an experienced orthopedic surgeon (group B).

Secondary Objective:
To compare the operative time, complications, and patient-reported outcomes of PSI PROPHECY*TAR between a beginning (group A) and an experienced orthopedic

surgeon (group B).

Study design

Single center cross-sectional observational study.

Study burden and risks

The risk of participation is limited to the standard risk of electromagnetic radiation used for CT scanning without contrast fluids. By participating, a participant will twice endure an additional effective dose (ED) of around 0.23 mSv, which corresponds with 14% of one year*s standard Dutch environmental dose of radiation. The patient may in a few situations benefit from the additional CT scan. If the patient is having complaints of the limb, the CT scan may reveal a possible cause. If during the process novel asymptomatic abnormalities or illnesses are suspected, the patient will be informed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient can understand the study's meaning and is willing to sign the study-specific Informed Patient Consent Form.
- Patient received the implantation of Infinity or Inbone prosthesis using PROPHECY PSI for primary TAR in 2021-2023.
- There are at least 3 months of follow-up data for this patient.
- Patient can lay still during the length of duration of the CT-scan.

Exclusion criteria

- If per-operative the use of the PSI guides was abandoned.
- Patients that underwent revision surgery (defined as original tibia of talar component change or removal).
- Patients that endured other diseases that significantly impacted the post-operative period following TAR (e.g. amputation, severe extremity dysfunction due to a neurological or vascular impairment or trauma).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-05-2024
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	PROPHECY Preoperative Navigation Guides and Patient-Specific Instrumentation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-06-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL83260.018.22