A Prospective, Multi-Center, Randomized Clinical Study of Total Shoulder Arthroplasty Comparing Exactech Guided Personalized Surgery (GPS) vs. Conventional Instrumentation

Published: 13-06-2024
Last updated: 27-12-2024

The purpose of this clinical study is to evaluate a multitude of factors that may influence clinical outcomes when performing primary reverse shoulder arthroplasty (RSA) with the Exactech Guided Personalized Surgery (GPS , Exactech, Gainesville, FL...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON56814

Source
ToetsingOnline

Brief title
TSA with Exactech with GPS or conventional instrumentation: an RCT

Condition

- Joint disorders

Synonym
fractures near the shoulder joint, Shoulder degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Exactech, Inc.
Source(s) of monetary or material Support: Exactech Inc.

Intervention

Keyword: Personalized surgery, Randomized clinical study, Shoulder arthroplasty

Outcome measures

Primary outcome

Alignment of the prosthesis (i.e., degree of accurate implant placement

according to plan, using a postoperative CT scan to confirm position).

Secondary outcome

American Shoulder and Elbow Surgeons Standardized Shoulder Assessment (ASES)

Form and range of motion measurements at 3 months, 1 year, 2- year, 5-year, and

10-year postoperative timepoints.

Radiographic outcomes from scans (e.g., radiolucent lines, notching, etc.)

Study description

Background summary

It is hypothesised that patients receiving a primary reverse shoulder arthroplasty will have better shoulder alignment in terms of glenoid implant placement in mm and angulation (version and inclination) with respect to the preoperative plan with the GPS technique compared to the conventional technique. Furthermore, it is hypothesised that patients receiving a primary reverse shoulder arthroplastywill demonstrate better patient reported outcomes (ASES) and ROM measurements (e.g. active abduction and active forward flexion) with the GPS technique compared to the conventional technique.

Study objective

The purpose of this clinical study is to evaluate a multitude of factors that may influence clinical outcomes when performing primary reverse shoulder

arthroplasty (RSA) with the Exactech Guided Personalized Surgery (GPS , Exactech, Gainesville, FL) compared to conventional instrumentation.

Study design

This is a prospective, multi-center, clinical study with three phases: 1) Non-Randomized Conventional Cohort, 2) Exactech GPS Training Cohort, and 3) Randomized Cohorts.
1) Non-Randomized Conventional Cohort, 2) GPS Training Cohort, 3) Randomized Cohorts
Each surgeon investigator will participate in all three phases with the same shoulder system. In order to benchmark their conventional technique, the Non-Randomized Conventional Cohort, each surgeon will conduct 10 consecutive cases using their conventional technique. Next, to learn the Exactech GPS® system, GPS Training Cohort, each surgeon will conduct 10 consecutive cases using the GPS technique. Once Phase 1 and Phase 2 are completed, the surgeon can progress to the Randomized Cohorts, Phase 3.

Intervention

Implantation of Equinoxe® Shoulder System.
Since patients enrolled in this study will only have reverse shoulder arthroplasty surgery, only reverse shoulder components will be used.

In one study arm, the Exactech GPS® will be used. Exactech GPS® is a navigation system used for implantation of Exactech shoulder prostheses.
In the second study arm, conventional instrumentation will be used.

Study burden and risks

Within the framework of the study, an additional CT scan will be performed. A CT scan exposes the subject to radiation. The total radiation dose from a CT scan is about three times the amount of radiation the subject is normally exposed to in one year ("background radiation").

Contacts

Public
Exactech, Inc.

NW 66th Court 2320
Gainesville, Florida 32653 32653
US
Scientific

Exactech, Inc.

NW 66th Court 2320
Gainesville, Florida 32653 32653
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient is at least 21 years of age at the time of surgery.
Patient is indicated for reverse shoulder arthroplasty.
Patient is willing to participate by complying with pre- and postoperative visit requirements.
Patient is willing to participate for the entire length of the prescribed follow-up (minimum 2 years).
Patient is willing and able to review and sign a study informed consent form.
Preop CT scan is within 3 months of the date of surgery.

Exclusion criteria

Revision shoulder arthroplasty.
Reverse shoulder arthroplasty for fracture.
Need for structural glenoid bone graft.
Osteomyelitis of the proximal humerus or scapula; if a systemic infection or a secondary remote infection is suspected or confirmed, implementation should be delayed until infection is resolved.
Inadequate or malformed bone that precludes adequate support or fixation of the prosthesis.
Neuromuscular disorders that do not allow control of the joint.
Significant injury to the brachial plexus.

Non-functional deltoid muscles.
The patient is unwilling or unable to comply with the post-operative care instructions.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-06-2024
Enrollment:	220
Type:	Anticipated

Medical products/devices used

Generic name:	Equinoxe® Shoulder System / Exactech GPS Platform
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-06-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL81649.058.22