Thumb Hemi-Arthroplasty with Natural Kinematics; a Prospective Multicenter Study to Confirm the Safety and Efficacy of the InDx Implant (THANKS PRO)

Published: 18-07-2024
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The purpose of the investigation is to confirm the safety and efficacy of the InDx implant in treatment of CMC osteoarthritis.

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

Summary

ID

NL-OMON56967

Source
ToetsingOnline

Brief title
THANKS PRO

Condition

- Joint disorders

Synonym
arthrosis of the thumb base joint, Thumb CMC arthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Loci Orthopaedics Ltd
Source(s) of monetary or material Support: Sponsor (Loci Orthopaedics)

Intervention

Keyword: Hemi-arthroplasty, InDx Implant, Thumb CMC joint

Outcome measures

Primary outcome

Primary safety endpoint: adverse events related to the device which lead to a

total revision.

Primary endpoint efficacy: outcome functional performance per DASH and PRWHE

questionnaires.

Secondary outcome

Secondary endoints:

- Thumb ROM

- Pinch force (tip pinch and latral pinch)

- Grip force

Also see section 4.2 of the CIP.

Study description

Background summary

Carpometacarpal (CMC) osteoarthritis (OA), particularly prevalent in postmenopausal women over 65. CMC osteoarthrosis is a degenerative condition causing pain, stiffness, and weakness. It affects a significant portion of the elderly population, with 17-33% of elderly women and 5-11% of men showing evidence of CMC OA. Severe thumb base arthritis impacts 5% of the population, translating to over 40 million people in the US and EU alone.
Besides the symptoms as described above, CMC osteoarthrosis symptoms also include reduced motion range of the thumb and decreased grip and pinch strength, hindering daily activities.
Treatment options vary from conservative approaches (lifestyle change, physical

therapy, splinting, medication) to a surgical intervention. The most common intervention is a trapeziectomy, in which the trapezium is removed. Disadvantages in general are reduced range of motion of the thumb and a decrease in force and functionality of the hand. A substantial decrease in pain is not always achieved. Total- or hemiarthroplasty procedures are also done with a number of devices which are already on the market, but treatment with these devices also has it's disadvantages (see section 1.1 of the CIP).
The InDx implant is designed to accomodate the natural biomechanics of the thumb joint, aiming for a stable fixation within the joint to prevent loosening or subluxation.

Study objective

The purpose of the investigation is to confirm the safety and efficacy of the InDx implant in treatment of CMC osteoarthritis.

Study design

This is a prospective, multi-center non-comparative study.

Intervention

The intervention is a hemiarthroplasty with the InDx implant, instead of a trapeziectomy. The subjects would have been scheduled for a surgical intervention anyway.

Study burden and risks

The study participants were already eligible for surgical intervention due to complaints regarding thumb base arthritis. The most common intervention (trapeziectomy, removal of the trapezium) has a number of disadvantages and the outcome usually includes limitations of hand functionality and non-substantial decrease of pain. Treatment with the InDx implant could provide a possible improvement.
The additonal burden to the subjects are addtional tests for grip and pinch strength and addtional questionnaires. There no addtional invasive tests required.
The riscs as described in section E9 are mitigated bu thourough training of the surgeons and frequent follow-up after the surgery. Most risks that are directly linked to the implant can be reversed by performing a trapeziectomy in extreme cases after removal of the implant.

Contacts

Public
Loci Orthopaedics Ltd

Unit 4, Business Innovation Centre, NUI Galway 4
Galway H91 H2Y0
IE
Scientific
Loci Orthopaedics Ltd

Unit 4, Business Innovation Centre, NUI Galway 4
Galway H91 H2Y0
IE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

A. The patient is at least 18 years of age;
B. The patient has a confirmed Grade I-III osteoarthritis of the CMC joint on clinical examination and X-ray;

Exclusion criteria

A. The patient is suffering from Rheumatoid arthritis in the index hand;
B. The patient is suffering from Grade IV osteoarthritis of the CMC joint;
C. The patient is suffering post-traumatic arthritis of the CMC joint in the index hand;
D. The patient is a pregnant/lactating female (tested as per institutional

requirements);
E. Active or latent infection, or sepsis;
F. Insufficient quantity or quality of bone and/or soft tissue in the index hand;
G. Metal or polymer material sensitivity;
H. Muscular imbalance, peripheral vascular disease that prohibits adequate healing, or a a poor soft-tissue envelope in the surgical field, absence of musculoligamentous supporting structures, or peripheral neuropathy;
I. Patient with previous thumb surgery in the index hand
J. In the opinion of the investigator, any medical condition that makes the subject unsuitable for inclusion in the study, including, but not limited to
a. Patients with a diagnosis of concomitant injury that may interfere with healing
b. Patients with clinically significant renal, hepatic, cardiac, endocrine, hematologic, autoimmune, or any systemic disease or systemic infection that may make interpretation of the results difficult
K. Patients who have undergone systemic administration within 30 days prior to implantation of any type of corticosteroid, antineoplastic, immunostimulating, or immunosuppressive agents;
L. Comorbidity that reduces life expectancy to less than 36 months;

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-02-2025
Enrollment:	36
Type:	Anticipated

Medical products/devices used

Generic name:	InDx implant

Registration:	No

Ethics review

Approved WMO Date:	18-07-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL86290.000.24